Supreme Court, U.S.
FILED
04 437 SEP 29 2004
OFFICE OF THE CLERK

No. 04-

IN THE

Supreme Court of the United States

WYETH,

Petitioner,

v.

LINDA SMART, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

ROBERT D. ROSENBAUM
JEROME I. CHAPMAN
SARAH M. BRACKNEY
RICHARD KORNYLAK
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
(202) 942-5862

PETER L. ZIMROTH
Counsel of Record
ARNOLD & PORTER LLP
399 Park Avenue
New York, NY 10022
(212) 715-1010

Counsel for Petitioner

189929

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTIONS PRESENTED

1. Whether the Court of Appeals gave undue deference to state courts in restricting the power of federal courts effectively to enforce their own judgments and protect their own jurisdiction over class action settlements which impose limitations on class members' state court lawsuits.

2. Whether the Court of Appeals misperceived this Court's decisions in *Amchem Products Inc. v. Windsor*, 521 U.S. 591 (1997), *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), and *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985), concerning due process principles governing class action notices and thereby undermined the viability and enforceability of federal class action settlements by construing their terms against the settling defendant.

PARTIES TO THE PROCEEDING BELOW AND RULE 29.6 STATEMENT

Petitioner Wyeth has no parent company, and no publicly held company owns more than 10 percent of Wyeth's stock.

Respondents are Linda Smart, Clara Clark, George M. Fleming, Fleming & Associates, L.L.P., Mike O'Brien, Michael C. Abbott, Keith K. Barlow, Ruby S. Barlow, Cherry Barnes, Joe Wayne Burton, Nora K. Burton, Lonelle S. James, Michael J. Miller, Kenneth W. Smith, Miller & Associates, Edward A. Williamson, Fenton B. DeWeese, II, The Law Office of Edward A. Williamson, Merrida Coxwell, Charles R. Mullins, Coxwell & Associates, PLLC, Eugene C. Tullos, Linda Eichmiller, Brenda Cook, Richard Cook, Doris Caldwell, Susan McCarty, Jim McCarty, Jr., Julia Campbell, Carolyn Winters, Bobby G. Winters, Macy Houston, and John F. Houston.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
PARTIES TO THE PROCEEDING BELOW AND RULE 29.6 STATEMENT	ii
TABLE OF CONTENTS	iii
TABLE OF CITED AUTHORITIES	v
TABLE OF APPENDICES	viii
OPINIONS BELOW	1
STATEMENT OF JURISDICTION	1
STATUTORY PROVISIONS INVOLVED	1
INTRODUCTION	2
STATEMENT OF THE CASE	3
A. The Class Action Settlement	3
B. Respondents' Lawsuits and the District Court's Injunctions	6
C. The Court of Appeals' Reversal	7

Contents

	Page
REASONS FOR GRANTING THE PETITION ...	12
SUMMARY	12
I. THE COURT OF APPEALS' DECISION PRESENTS AN IMPORTANT QUESTION BECAUSE IT IMPROPERLY BALANCES THE RESPECTIVE ROLES OF THE FEDERAL AND STATE COURTS IN ENFORCING A FEDERAL COURT CLASS ACTION SETTLEMENT	14
II. THE COURT OF APPEALS' DECISION PRESENTS AN IMPORTANT QUESTION BECAUSE IT MISPERCEIVED THIS COURT'S PRIOR TEACHINGS ON THE DUE PROCESS REQUIREMENTS FOR CLASS NOTICES AS REQUIRING AN UNDULY CONSTRICTED READING OF SETTLEMENT AGREEMENTS	21
CONCLUSION	25

TABLE OF CITED AUTHORITIES

Page

Cases

Amchem Prods. Inc. v. Windsor, 521 U.S. 591 (1997) ..... *passim*

In re Airline Ticket Comm'n Antitrust Litig., 268 F.3d 619 (8th Cir. 2001) 24

In re Cendant Corp. PRIDES Litig., 233 F.3d 188 (3d Cir. 2000) 23

In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig., MDL No. 1203, 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000) 3, 4, 5, 6

In re Holocaust Victim Assets Litig., 282 F.3d 103 (2d Cir. 2002) 24

Int'l Longshoremen's Ass'n v. Philadelphia Marine Trade Ass'n, 389 U.S. 64 (1967) 20

Livingstone v. N. Belle Vernon Borough, 91 F.3d 515 (3d Cir. 1996) 23

Ortiz v. Fibreboard Corp., 527 U.S. 815 (1999) ..... i, 9, 22

Phillips Petroleum Co. v. Shutts, 472 U.S. 797 (1985) ..... i, 9, 22

Cited Authorities

Page

Pretrial Order No. 3888, MDL 1203 (E.D. Pa. Aug. 30, 2004) 11

Pretrial Order No. 3962, MDL 1203 (E.D. Pa. Sept. 22, 2004) 11

Schmidt v. Lessard, 414 U.S. 473 (1974) 20

United States v. New York Telephone Co., 434 U.S. 159 (1977) 21

Statutes

28 U.S.C. § 1254(1) 1

All Writs Act, 28 U.S.C. § 1651(a) 1, 7, 21

Anti-Injunction Act, 28 U.S.C. § 2283 ..... *passim*

Rules

FEDERAL RULES OF CIVIL PROCEDURE 23(c)(2)(B) ... 25

FEDERAL RULES OF CIVIL PROCEDURE 65(d) 19, 20

Cited Authorities

Page

Other Authorities

Alex Raskolnikov, Note, *Is There a Future for Future Claimants After Amchem Products, Inc. v. Windsor?*, 107 YALE L.J. 2545 (1998) 15

Francis E. McGovern, *Settlement of Mass Torts in a Federal System*, 36 WAKE FOREST L. REV. 871 (2001) 16

Richard A. Nagareda, *Autonomy, Peace, and Put Options in the Mass Tort Class Action*, 115 HARV. L. REV. 747 (2002) 16

Treatises

13 WILLISTON ON CONTRACTS § 38:15 (4th ed. 2000) 22

2 CORBIN ON CONTRACTS § 5.27 (rev. ed. 1995) 22

Herbert B. Newburg & Alba Conte, NEWBURG ON CLASS ACTIONS § 11.53 (3d ed. 1992) 24

RESTATEMENT (SECOND) OF CONTRACTS § 205 (1981) 23

TABLE OF APPENDICES

Page

Appendix A — Opinion Of The United States Court Of Appeals For The Third Circuit Dated May 25, 2004 ..... 1a

Appendix B — Memorandum And Pretrial Order No. 3088 Of The United States District Court For The Eastern District Of Pennsylvania Dated October 30, 2003 ..... 56a

Appendix C — Pretrial Order No. 2883 Of The United States District Court For The Eastern District Of Pennsylvania Dated June 10, 2003 ..... 64a

Appendix D — Memorandum And Pretrial Order No. 2828 Of The United States District Court For The Eastern District Of Pennsylvania Dated April 8, 2003 ..... 69a

Appendix E — Memorandum And Pretrial Order No. 2717 Of The United States District Court For The Eastern District Of Pennsylvania Dated January 29, 2003 ..... 125a

Appendix F — Memorandum And Pretrial Order No. 2680 Of The United States District Court For The Eastern District Of Pennsylvania Dated December 11, 2002 ..... 135a

Appendices

Page

Appendix G — Memorandum And Pretrial Order No. 2625 Of The United States District Court For The Eastern District Of Pennsylvania Dated October 16, 2002 ..... 146a

Appendix H — Order Of The United States Court Of Appeals For The Third Circuit Denying Petition For Rehearing Dated June 29, 2004 ..... 155a

Petitioner Wyeth respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Third Circuit in this case.

OPINIONS BELOW

The opinion of the Court of Appeals is reported at 369 F.3d 293 (2004) and is reproduced in the appendix (App. at 1a-55a). The United States District Court for the Eastern District of Pennsylvania issued six injunctions that were reviewed by the Third Circuit. Those orders are unreported and are reproduced in the appendix (App. at 56a-154a). The order of the Court of Appeals denying petitioner's petition for rehearing and for rehearing en banc is unreported and is reproduced in the appendix (App. at 155a-157a).

STATEMENT OF JURISDICTION

The judgment of the Court of Appeals was entered on May 25, 2004. Petitioner's timely petition for rehearing was denied on June 29, 2004. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The All Writs Act, 28 U.S.C. § 1651(a), provides that:

> The Supreme Court and all courts established by Act of Congress may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law.

The Anti-Injunction Act, 28 U.S.C. § 2283, provides that:

> A court of the United States may not grant an injunction to stay proceedings in a State court except as expressly authorized by Act of Congress, or where necessary in aid of its jurisdiction, or to protect or effectuate its judgments.

INTRODUCTION

The Court of Appeals' decision has widespread implications for the respective roles of the federal and state judiciaries in enforcing federal court class action settlements of mass tort claims. The settlement at issue here permits class members to sue Wyeth in state or federal court if they were unaware of their injury at the time of the settlement, but bars class members from seeking punitive or similar non-compensatory damages in their suits. Even though the settlement expressly vests "continuing and exclusive" jurisdiction in the District Court to enforce its terms, the Court of Appeals' decision severely limits the power of the federal settlement court to prevent respondents' blatant attempts to evade the punitive damages bar in their state court lawsuits. The Court of Appeals shifted to those state courts the responsibility for interpreting and enforcing the federal court settlement. The Court of Appeals' unprecedented conclusion that this result is required by principles of federalism and comity is contrary to law and elevates those principles above the paramount requirement that a federal court must have the ability to protect its own jurisdiction and effectuate its own judgment. Petitioner respectfully urges this Court to hear this case and correct that improper balance.

This case has broader implications than merely the particular settlement at issue here, although there are approximately 30,000 class members with similar suits pending in state courts at this time. Professor John Coffee testified that this Settlement "should be and will be the model for the future for dealing with large scale mass torts."[1] That is so, he testified, because this settlement, by permitting subsequent class member lawsuits, "does not run afoul of any of the concerns" expressed by this Court in *Amchem Products Inc. v. Windsor*, 521 U.S. 591 (1997), about binding class members unaware of an injury.[2] The Court of Appeals' decision here, however, will be the death knell of this innovative settlement structure.

STATEMENT OF THE CASE

A. The Class Action Settlement

In September 1997, Wyeth ceased marketing two prescription anti-obesity medications, Pondimin and Redux, in response to reports associating those drugs with valvular heart disease ("VHD"), a disease of the aortic or mitral valve of the heart. After two years of extensive litigation involving thousands of lawsuits, Wyeth entered into a nationwide class action settlement agreement (the "Settlement"). The District Court approved the Settlement. *See In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, MDL No. 1203, 2000 WL 1222042 (E.D. Pa. Aug. 28,

---

1. Tr. of Fairness Hearing of May 3, 2000 (Coffee), at 237 (Docket No. 99-20593 (E.D. Pa.), entered June 28, 2000, at 1051 of MDL-1203).

2. *Id.* at 236.

2000) (order approving settlement). The class encompasses all persons in the United States who had used either of those drugs, almost 6 million people.

Wyeth agreed to pay up to $3.75 billion under the Settlement. A portion of those funds supports a nationwide medical monitoring program. Qualifying class members found to have VHD may receive substantial compensation under the Settlement. In the alternative, if they were unaware of their injury at the time of the Settlement and learn of such an injury through the Settlement's medical monitoring program or otherwise, they may then exercise an "Intermediate Opt-Out" or similar right (referred to here as "IOO") and sue Wyeth in the tort system for compensation. In approving the Settlement, the District Court explained that it "provides multiple opportunities for class members to gain information concerning the injuries they have suffered as a result of taking Pondimin and Redux and to opt-out of the settlement in light of the information gained through those opportunities." *In re Diet Drugs*, 2000 WL 1222042, at *25.

IOO plaintiffs remain class members, and their lawsuits are governed by provisions of the Settlement in a number of respects. For example, the Settlement permits IOO plaintiffs to sue only based on VHD and not based on any other condition. IOO plaintiffs may not assert claims for consumer fraud or medical monitoring. And the Settlement restricts certain uses of any prior verdict, judgment or factual finding.

Moreover, and of central importance to the Settlement, it provides that an IOO plaintiff "may not seek punitive,

exemplary, or any multiple damages." JA at 616.[3] In return, Wyeth agreed, among other things, not to assert the statute of limitations against IOO plaintiffs. The District Court found, in approving the Settlement, that the prohibition against punitive, exemplary or multiple damages "represents a fair and wholly appropriate trade-off" in light of the significance of Wyeth's waiver of limitations defenses. *In re Diet Drugs*, 2000 WL 1222042, at *49 n.22. That waiver "serve[s] to protect the class against some of the main risks they face toward recovery." *Id.*

Before approving the Settlement, the District Court directed an extensive notice plan, including broadcasts on network and cable television and on radio, publication in newspapers and in many magazines, and an enormous mailing of Notice packages. The Notice package explained the medical issues relating to VHD and summarized in some detail the complex provisions of the Settlement. The Notice outlined the options available to class members, including their right to opt out of the class at that time as well as the availability of possible IOO rights at a later time. The Notice emphasized the restrictions on IOO suits, including that they could "not seek punitive or multiple damages." App. at 31a (quoting Notice).

The Settlement provided, as a condition to Wyeth's obligations, that the District Court must retain "continuing and exclusive" jurisdiction "to administer, supervise, interpret, and enforce [the Settlement] in accordance with its terms." JA at 699-700. Upon approving the Settlement, the District Court accordingly entered an order retaining

---

3. Citations to the Joint Appendix submitted to the Third Circuit will be cited as "JA at __."

exclusive jurisdiction, including jurisdiction "to enter such other and further orders as are needed to effectuate the terms of the Settlement." *In re Diet Drugs*, 2000 WL 1222042, at *72.

B. Respondents' Lawsuits and the District Court's Injunctions

Class member-respondents Clara Clark and Linda Smart chose not to opt out of the class. They subsequently exercised IOO rights, however, and sued Wyeth in Orange, Texas and in Alice, Texas, respectively, based on alleged VHD. They proceeded to litigate their claims in a manner that made clear they sought more than compensatory damages in order, as they admitted in open court, to obtain "moral vindication." JA at 2574. While their complaints did not explicitly assert a claim for punitive damages, the District Court found that "what [Mr. Fleming, their common counsel] is not doing in name, he is doing in substance" by means of inflammatory evidence and arguments designed to inflate an award for pain and suffering. App. at 138a.

The District Court first enjoined Mss. Clark and Smart and their attorney from using evidence or arguments designed to obtain punitive, exemplary or multiple damages. App. at 146a-154a (Clark) and 135a-145a (Smart). They flouted and evaded those injunctions, making clear their continued intent to seek punitive or exemplary damages in substance if not in name. *See* App. at 125a-134a. They argued they did not know what specifically they were enjoined from doing because of the general wording of the injunctions. After three separate such incidents in the *Clark* and *Smart* cases, *id.*, the District Court found that their counsel was engaged in "a blatant

assault aimed at flouting [the prior injunction] of this court and undermining the carefully crafted" Settlement. App. at 130a.

Because of such persistent and provocative behavior, and in order to "eliminate as much chance for evasion as possible," the District Court found it necessary to review respondents' trial plan with the parties. App. at 74a, 133a-134a. Based on that review, the Court made detailed rulings, enjoining specific evidence or categories of evidence whose "sole or predominate purpose" the Court found was to "inflam[e] the jury to punish Wyeth. . . ." App. at 73a. The Court ruled that certain other evidentiary questions would be left to the state trial court. *See, e.g.*, App. at 76a. *See generally* App. at 69a-124a.

The other respondents had also exercised IOOs, had sued in state courts in Mississippi and Georgia, and had proposed to use the same evidence as that proffered in the *Clark* and *Smart* cases. The District Court subsequently issued virtually identical injunctions against those respondents as were issued against respondents Clark and Smart. App. at 64a-68a and 56a-63a.

C. The Court of Appeals' Reversal

The Third Circuit Court of Appeals found that the District Court had the power to issue these injunctions under the All Writs Act, 28 U.S.C. § 1651(a), and an exception to the Anti-Injunction Act, 28 U.S.C. § 2283. The Court referred to the Settlement as "a landmark effort to reconcile the rights of millions of individual plaintiffs with the efficiencies and

fairness of a class-based settlement. Critical to this effort," the Court continued,

> was the allowance of [IOOs], so that potential class members were not faced with an all-or-nothing decision at the threshold. To make this allowance meaningful, the settlement had to protect Wyeth against its largest fear, potentially ruinous punitive damage awards. At the same time, it had to allow [IOOs] to have a fair chance to litigate their claims and obtain those damages that were expressly preserved.

App. at 51a. The Court found "justifiable" the District Court's concern "that the plaintiffs were seeking to obtain through the back door what they were barred from receiving through the front." App. at 12a. The Court acknowledged that "the punitive damages release is a central pillar" of the Settlement and that the District Court must have the power to give effect to that provision if the Settlement and the District Court's jurisdiction are not to be rendered "nugatory." App. at 27a. The Court of Appeals found that the District Court had entered the injunctions at issue "in order to protect the settlement against guerilla warfare from the opt-out lawyers." App. at 22a.

The Court of Appeals nevertheless found that the District Court had erred in entering the injunctions at issue, except to the extent that they prohibited the use of evidence relevant "exclusively" to punitive damages, *i.e.*, evidence about Wyeth's sales, profits and net worth. App. at 40a.

(1) The Court of Appeals concluded that the injunctions went too far over "appropriate boundaries in relation to state

courts." App. at 7a. The injunctions "disrupt[ed] the state court's ability to manage its own judicial process" and failed to "minimize[] entanglement in the state judge's ability to supervise judicial proceedings in his own courtroom." App. at 50a-51a. The District Court had "effectively adopted the role of a trial judge balancing probative value against unfair prejudice" and had therefore unduly intruded into the state court's function. App. at 44a. For essentially the same reason, the Court of Appeals also found that the injunctions were not "workable." App. at 47a-51a.

(2) To the extent the injunctions barred the use of evidence which was not only related to punitive damages but which was also probative of liability, causation or compensation, the Court of Appeals also stated that those orders were "not fairly comprehended within the terms of the settlement agreement and class notice." App. at 7a. This was so even if such evidence was offered, as the District Court had found, for the "sole or predominant purpose" of inflaming the jury to punish Wyeth. App. at 73a. The Court of Appeals found it necessary to "strictly construe" the Settlement's restrictions, largely based on its understanding of this Court's emphasis on due process constraints on the binding effect of class action settlements on absent class members in *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 845-48 (1999); *Amchem Prods. Inc. v. Windsor*, 521 U.S. 591, 620 (1997); and *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 812 (1985). App. at 5a. Although the class Notice here clearly advised class members of the restriction against their seeking punitive, exemplary or multiple damages, the Court was concerned that the Notice did not expressly tell class members that this restriction could have an impact on their strategy in litigating compensatory damages. The Court of Appeals therefore indicated that the Settlement should not

be interpreted as permitting the District Court to prohibit class members' use of evidence probative of compensatory damages, even if offered for the sole or predominant purpose of inflaming the jury so that it awards inflated damages.[4]

(3) Nevertheless, the Court of Appeals acknowledged that the Settlement does in fact preclude the use of tactics by class members to inflame the jury in order to obtain an inflated compensatory damage award. The state court, said the Court of Appeals, had an obligation under the Settlement to preclude the use of such tactics. The federal settlement court, however, could not do so. In a comment which goes to the heart of the decision, the Court observed that, while it had limited *the District Court's* ability to do so,

> *the state courts* are presumably mindful of the obligation to honor the settlement agreement, and to ensure that the parties do not evade it. That will undoubtedly impel the state courts during trial to exclude evidence when its prejudicial effect (namely its tendency to inflame the jury and

4. In the *Clark* and *Smart* state court actions, Wyeth had offered to stipulate that, in order to obtain a judgment against it, those respondents would not need to demonstrate that Wyeth breached a duty or that its drugs could cause VHD, thereby eliminating any need for evidence probative of Wyeth's fault. Respondents would only need to show that they had VHD, that it was in fact caused by Wyeth's drugs (rather than by a number of other widely-known causes) and the amount of their damages. The state court in *Smart* accepted that proposal, but the state court in *Clark* rejected it, while suggesting that a different type of stipulation might be acceptable. The Court of Appeals mistakenly stated that Wyeth did not offer the type of stipulation suggested by that Court. App. at 17a-18a, 45a-46a. But Wyeth did in fact submit a revised stipulation in *Clark* that incorporated the state judge's suggestions. JA at 3425, 3428, 3429, enclosing proposal at 3426-27.

> improperly inflate compensatory damages) outweighs its probative value.

App. at 53a (emphasis added). The Court of Appeals also stated that the District Court was "free to consider other measures," aside from imposing evidentiary restrictions, "that will effectuate the limitations of the settlement agreement." App. at 53a. One example offered by the Court of Appeals was that the District Court could consider ordering the parties to stipulate to a bifurcated trial in which damages are determined apart from liability. The Court of Appeals made clear, however, that, even as to this alternative form of possible relief, the federal court would be subservient to the state courts. The Court of Appeals stated that this form of relief would only be permissible "in the event that the state court were to deem it advisable." App. at 53a.

The Court of Appeals vacated the District Court's injunctions and remanded with instructions to modify them "in accordance with this opinion." App. at 55a.[5]

---

5. Upon remand, the District Court has modified its injunctions to require the parties to stipulate to bifurcation in their state court trials, as suggested by the Court of Appeals, although, pursuant to its decision, "the state trial judge would have the final word." Pretrial Order No. 3888, MDL 1203 (E.D. Pa. Aug. 30, 2004), at 5. It is not yet known whether those state courts will approve such bifurcated trials. The respondents have already filed a further appeal to the Third Circuit Court of Appeals from those modified injunctions and have also filed a petition for writ of mandamus in that Court, arguing that the modified injunctions are inconsistent with the Third Circuit's decision. *See* Docket Nos. 04-3591 (appeal) and 04-3643 (petition for mandamus). The District Court stayed the effectiveness of its order, as to any plaintiff who obtains a postponement of his or her trial until after the Court of Appeals has ruled on that appeal and that petition. Pretrial Order No. 3962, MDL 1203 (E.D. Pa. Sept. 22, 2004). The Court of Appeals has expedited its consideration of the appeal and the mandamus petition.

Wyeth's petition for rehearing en banc was denied. Wyeth thereupon timely filed this Petition for Writ of Certiorari, seeking review of the Court of Appeals' order.

REASONS FOR GRANTING THE PETITION

Summary

The Court of Appeals' decision improperly balances the respective roles of the federal and state courts in enforcing a federal court class action settlement. The Court of Appeals found that, even to enforce its own judgment and protect its own jurisdiction, the District Court unduly intruded into state court proceedings to prevent respondents' "guerilla warfare" against the "central pillar" of the Settlement. Based on a misguided view of principles of federalism and comity, the Court of Appeals essentially left to the state trial judges the job of enforcing the federal settlement in their respective trials, at least to the extent that respondents' circumvention took the form of using unduly inflammatory evidence. But nothing in the Anti-Injunction Act, 28 U.S.C. § 2283, and nothing in any of this Court's jurisprudence suggests that principles of federalism and comity should predominate over the ability of a federal court effectively to rein in the type of blatant disregard and circumvention of its own judgment and orders reflected here.

Moreover, any intrusion into state court proceedings arising from the orders at issue here is a necessary consequence of the fact that this federal court judgment permits state court lawsuits but subjects them to crucial restrictions. If this type of settlement structure is ever to be used again, defendants must be assured that the federal

settlement court has the power and the recognized flexibility to take action needed to protect the defendant against evasion of the punitive damages bar, even if some intrusion into state court proceedings is an unavoidable consequence. Principles of federalism and comity in this context must be applied in light of the necessity of giving the federal settlement court not only the theoretical power, but also the practical ability to take such actions. Otherwise, federal courts will not only be deprived of the capability to protect their own jurisdiction and their own judgments, but they will also be deprived of the viability of this type of settlement agreement for use in resolving mass torts.

This Petition should also be granted because of the widespread implications of the Court of Appeals' erroneous indications that due process considerations required the suspension of the normal principles of contract construction and interpretation in enforcing a class action settlement agreement. The Court of Appeals explained that, because the notice sent to class members did not explicitly tell them they would be prohibited from depriving Wyeth of the benefit of its bargain by attempting to evade the Settlement's restrictions, class members would only be held to the Settlement's express restrictions, "strictly construed." But there is nothing unfair, and certainly nothing rising to the level of a due process concern, about preventing class members from attempting to end-run express restrictions merely because the class notice did not spell out that they would be precluded from doing so.

I. THE COURT OF APPEALS' DECISION PRESENTS AN IMPORTANT QUESTION BECAUSE IT IMPROPERLY BALANCES THE RESPECTIVE ROLES OF THE FEDERAL AND STATE COURTS IN ENFORCING A FEDERAL COURT CLASS ACTION SETTLEMENT

The Court should grant this Petition because the Court of Appeals' decision, based on a misguided view of federalism and comity, essentially negated the District Court's retention of exclusive jurisdiction to enforce a federal court settlement and severely restricted the District Court's ability to enforce its own judgment.

The Court of Appeals acknowledged that the District Court had the power to enforce its own judgment, which incorporated the Settlement. And the Court of Appeals agreed with the District Court that the relief it had ordered was an effective means to enforce a "central pillar" of the Settlement, namely class members' agreement not to seek punitive, exemplary or multiple damages. Moreover, the Court of Appeals, despite some parts of its decision which suggest the contrary, concluded by recognizing that the Settlement precludes class members from seeking to circumvent that restriction. *See* App. at 53a (the state courts are "presumably mindful of the obligation to honor the settlement agreement" by excluding evidence likely to "improperly inflate compensatory damages"). Yet the Court of Appeals found that principles of federalism and comity required that the enforcement of those restrictions in state court IOO suits must be left in the hands of the respective state trial courts. In the interest of avoiding impingement on what the Court of Appeals viewed as the prerogatives of those state trial courts, the Court of Appeals unduly diminished the legitimate, and

indeed necessary, authority of federal settlement courts to effectuate the provisions of their own judgments over which they have retained jurisdiction.

The Court of Appeals relied in part on its view that the state courts could be relied upon to prevent evasion of the Settlement by precluding evidence when its tendency to inflame the jury and improperly inflate compensatory damages outweighs its probative value. App. at 53a. But the point is not whether state courts can be trusted to enforce the Settlement. The critical point is that the orders at issue here enforced the District Court's own judgment. Any intrusion into state court proceedings arising from the entry of such an order is a necessary consequence of the fact that this federal court judgment permits state court lawsuits but subjects them to restrictions.

This type of settlement, which permits class members to withdraw and sue in the tort system, has been widely hailed as addressing the concerns expressed by this Court in *Amchem*. The Court there expressed grave reservations about the ability of mass tort plaintiffs to receive effective notice of class action settlements if they are unaware of any injury. 521 U.S. at 628-29. After that decision, commentators questioned whether mass tort class actions could ever be certified and settled where some injuries were unknown. *See, e.g.*, Alex Raskolnikov, Note, *Is There a Future for Future Claimants After Amchem Products, Inc. v. Windsor?*, 107 YALE L.J. 2545 (1998). Columbia Law School Professor John Coffee testified in support of the Settlement here, however, that it was

> the most sophisticated, innovative attempt to design something that does not run afoul of any

> of the concerns of *Amchem* or *Ortiz*. . . . I think that is probably the only way that a class action can deal with the mass tort phenomenon. This case, this proposed settlement I think should be and will be the model for the future for dealing with large scale mass torts."[6]

See also Richard A. Nagareda, *Autonomy, Peace, and Put Options in the Mass Tort Class Action*, 115 HARV. L. REV. 747, 796 (2002) (This Settlement is a "bold new approach."); Francis E. McGovern, *Settlement of Mass Torts in a Federal System*, 36 WAKE FOREST L. REV. 871, 883 (2001) (The diet drug settlement was commended as one of "[t]he most notable current examples" of "a settlement that will satisfy the dictates of Amchem and Ortiz.").

But critical to any defendant's willingness to pay billions of dollars in settlement and nevertheless permit class members to sue it in the state court tort system is protection against what Professor Nagareda said was "the most normatively troubling source of volatility for mass tort defendants: the prospect of duplicative punitive damage awards over time." Nagareda, 115 HARV. L. REV. at 797. The Court of Appeals here agreed, finding the restriction against class members' seeking punitive or similar damages to be a "central pillar" of the Settlement. App. at 27a.

The Court of Appeals nevertheless deprived the defendant of the mechanism for which it had bargained to ensure that that "central pillar" would not falter – the exclusive power of the federal court to enforce the restriction

---

6. Tr. of Fairness Hearing of May 3, 2000 (Coffee), at 236-37. *See supra* note 1.

on class members' seeking punitive or similar damages. The Court of Appeals recognized that that protection was gained as a trade-off "in return for" Wyeth's funding a nationwide medical monitoring program, permitting class members found to be injured to sue and waiving its powerful statute of limitations defenses in such suits. App. at 30a. The effective result of the Court of Appeals' decision, however, will be that class members' suits once barred by the statute of limitations will be resuscitated by the Settlement, while the adequacy of the defendant's protection against punitive damages in those suits will depend on the rulings made by each of the numerous state courts in which class members have brought their suits. There is of course no way to ensure that those state court rulings will be consistent or that all of those rulings will fully accord the defendant the protection for which it bargained.

Nothing in the Anti-Injunction Act or in any established principles of federalism and comity requires such a dramatic shift in the relative roles of the federal and state courts in enforcing federal class action settlements. This Court's review is warranted to restore the appropriate allocation of authority between the federal and state courts in that regard.

It is worthy of note that there are 30,000 class members who have exercised IOOs under the Settlement and are now litigating their claims against Wyeth in state courts. Approximately 100 of those claims are scheduled for trial in only the next few months, and other trials will start thereafter. The District Court was well aware of the broader implications of respondents' abuses. If these respondents are not enjoined, the District Court observed in a passage quoted with approval by the Court of Appeals, "the floodgates will be open, and the prohibition against punitive damages in the court

approved Settlement Agreement will be nothing but a dead letter." App. at 22a.[7]

The Court of Appeals' decision therefore represents the death knell for what has been hailed by Professor Coffee and others as a "model" for future mass tort class action settlements. No right-thinking defendant would ever enter into such a class action settlement under these circumstances. It is no secret that plaintiffs' attorneys in mass tort litigation generally seek out the most plaintiff-friendly state courts in the nation in which to bring their actions. As the Chamber of Commerce of the United States observed in its amicus brief to the Third Circuit Court of Appeals:

> If district courts cannot hold class members to their bargain, . . . then the wind will go out of the sails of this useful new vehicle for settling mass tort claims. *No defendant will agree to a settlement that allows futures plaintiffs to choose the higher of settlement-matrix benefits and tort-system remedies, when the defendant gains no real protection from having to pay even more than compensatory damages.*

Brief of Amicus Chamber of Commerce of the United States (July 11, 2003), at 19 (emphasis added).

---

7. After the Court of Appeals' decision vacating the injunctions, respondents' counsel participated in the issuance of a press release claiming that he could now use evidence to "outrage" future juries in the trials of 9,000 IOO plaintiffs he represents. Press Release, Majority Counsel, "Victims, Attorneys Praise New Ruling in Fen-Phen Litigation; Ruling Allows Key Evidence in Thousands of Heart Valve Cases, Says Majority Counsel" (May 26, 2004), www.forrelease.com/D20040 526/ daw036.P2.05262004183106.13851.html.

The circumstances presented here call, not for the application of deference and comity to state courts, but for the recognition that the federal settlement court's exclusive jurisdiction to interpret, enforce and effectuate its own judgment must be paramount. This is vital if the integrity of such settlements and the jurisdiction of the federal settlement courts are to be preserved. The All Writs Act and the Anti-Injunction Act reflect a fundamental policy that a federal court must be able to act "where necessary in aid of its jurisdiction, or to protect or effectuate its judgments," 28 U.S.C. § 2283, even if its order affects state court proceedings. The decision here, however, rests on the erroneous premise that considerations of federalism and comity require subordination of that fundamental policy.

That is not to say that the federal settlement courts should not strive to minimize the extent of their intrusion into state court proceedings. The District Court here, however, was impelled to fashion a very detailed injunction by the conduct of the respondents, who repeatedly claimed they did not understand what the District Court had required of them in prior, more general, injunctions. *E.g.*, JA at 2504-06. The Court of Appeals recognized, based on the record here, that respondents "repeatedly skirted the settlement and the District Court's orders, plainly seeking to inject prejudicial matter into the state court cases." App. at 21a. Indeed, the Court of Appeals referred to their conduct as "guerrilla warfare." App. at 22a.

Nevertheless, respondents repeatedly argued that they could not be held in contempt of the District Court's earlier and more general injunctions because those orders were

"inadequately precise" under Rule 65(d) of the Federal Rules of Civil Procedure to be enforceable.[8] The District Court expressly found, after a series of such incidents, that plaintiffs' counsel "has engaged in a pattern of evasion and lack of candor with this court." App. at 129a. The District Court ultimately concluded that

> [i]t has now become clear to the court that the only effective way to safeguard the Settlement Agreement is to enter a detailed order before trial outlawing specific topics of inquiry which have the sole or predominant purpose of inflaming the jury to punish Wyeth and excluding individual exhibits and deposition testimony going to the issue of punitive damages.

App. at 73a. Without such specificity, respondents undoubtedly would have once again refused to obey the order, claiming it was not sufficiently specific.

Federal settlement courts must have available a range of options to craft their orders as needed to meet the conduct at issue and to make those orders effective. As this Court held

---

8. *See, e.g.*, *Schmidt v. Lessard*, 414 U.S. 473, 476 (1974) (Rule 65(d) "was designed to prevent uncertainty and confusion on the part of those faced with injunctive orders, and to avoid the possible founding of a contempt citation on a decree too vague to be understood.") (citations omitted); *Int'l Longshoremen's Ass'n v. Philadelphia Marine Trade Ass'n*, 389 U.S. 64, 76 (1967) (same).

in *United States v. New York Telephone Co.*, 434 U.S. 159, 172 (1977), a federal court is empowered by the All Writs Act, 28 U.S.C. § 1651(a), and the Anti-Injunction Act, 28 U.S.C. § 2283, "to issue such commands . . . as may be necessary or appropriate to effectuate and prevent the frustration of orders it has previously issued in its exercise of jurisdiction otherwise obtained." If class members engage in the type of "guerilla warfare" as found here, the federal settlement courts must be recognized as having the ability to protect their own judgment and their continuing jurisdiction.

This Court should rule that federal settlement courts' authority over the enforcement of federal court class action settlements is and must be paramount, and that principles of federalism and comity must be subordinated to the effective ability of those courts to enforce their judgments.

II. THE COURT OF APPEALS' DECISION PRESENTS AN IMPORTANT QUESTION BECAUSE IT MISPERCEIVED THIS COURT'S PRIOR TEACHINGS ON THE DUE PROCESS REQUIREMENTS FOR CLASS NOTICES AS REQUIRING AN UNDULY CONSTRICTED READING OF SETTLEMENT AGREEMENTS

The Court should also grant this Petition because the Court of Appeals misperceived this Court's prior decisions concerning due process requirements for class action settlement notices. If allowed to stand, the Court of Appeals' decision is likely to have a significant and adverse effect on the administration of future federal court class action settlements.

The Court found that, in order to avoid the due process concerns expressed by this Court in *Amchem*, *Ortiz* and *Shutts*, restrictions on class members not expressly spelled out in either the class notice or the settlement agreement must be "strictly construed" against the settling defendant. App. at 5a, 30a-31a, 36a-37a. The Court therefore rejected the interpretation of the Settlement agreed to by all of (1) the Court-appointed counsel for the class who had negotiated the Settlement ("Class Counsel"), (2) Wyeth as the counterparty in those negotiations and (3) the District Court supervising the Settlement on an ongoing basis. None of those cases expressed any due process concern with the *content* of class notices, however, much less concerns which would justify such a constricted reading of class action settlement agreements.

It is unnecessary, if not impossible, for a class action settlement agreement governing conduct long into the future, as here, to anticipate and address every conceivable scenario in which persistent and clever attorneys for absent class members might seek to evade the settlement's restrictions. A settlement agreement is a contract, and it is a fundamental precept that all contracts contain an implicit obligation on each contracting party not to deprive the other party of the benefit of the bargain. 13 WILLISTON ON CONTRACTS § 38:15 (4th ed. 2000) ("The underlying principle is that there is an implied covenant that neither party will do anything which will have the effect of destroying or injuring the right of the other party to receive the fruits of the contract; in other words, in every contract there exists an implied covenant of good faith and fair dealing.").[9]

---

9. *See also* 2 CORBIN ON CONTRACTS § 5.27 (rev. ed. 1995) ("[E]very contract contains an implied obligation of good faith and fair dealing in its performance and enforcement."); RESTATEMENT

(Cont'd)

The relevant bargain here was that qualified class members could sue for compensation for specified injuries, but that they could not "seek" damages for the purpose of punishing Wyeth, making an example of it or multiplying the damages. When respondents engaged in "guerilla warfare" against the Settlement by attempting, among other things, to introduce all the same evidence and make all the same arguments as they had previously used in punitive damages trials, the District Court correctly found they were violating the Settlement. Under established principles of contract law, respondents were breaching their implied duty of good faith and fair dealing, whether or not they were also breaching the express terms of the Settlement. And when the District Court enjoined them from doing so, it was merely enforcing the express and implied terms of the Settlement.

Nevertheless, the Court of Appeals "strictly construed" the terms of the Settlement against Wyeth because it found that the court-approved class Notice did not adequately warn class members that the punitive damages restriction might impact on their strategy in litigating their compensatory damage claims. But there was nothing unfair, much less

---

(Cont'd)

(SECOND) OF CONTRACTS § 205 (1981) ("Every contract imposes upon each party a duty of good faith and fair dealing in its performance and its enforcement.") and cmt.d ("Subterfuges and evasions violate the obligation of good faith in performance. . . ."); *Livingstone v. N. Belle Vernon Borough*, 91 F.3d 515, 526 n.11 (3d Cir. 1996) ("The duty of good faith and fair dealing exists not only under federal common law, but also under Pennsylvania law.") (citations omitted). Settlement agreements are contracts, to be interpreted and construed under principles of contract law. *See, e.g., In re Cendant Corp. PRIDES Litig.*, 233 F.3d 188, 193 (3d Cir. 2000) ("[B]asic contract principles do indeed apply to settlement agreements. . . .").

bordering on a deprivation of due process, about enforcing an implied duty against evasion even if the Notice had no such statement. The Notice emphasized that IOO claimants would not be able to seek punitive or similar damages. App. at 31a. ("However, *it is important to understand that if you exercise the [IOO] and choose to bring a lawsuit against [Wyeth], your lawsuit will be subject to certain restrictions including the following:* . . . you may not seek punitive or multiple damages.") (emphasis in original). No class member could have thought in good faith that, without violating the Settlement, he or she could engage in the kind of "guerilla warfare" found here to evade that restriction and obtain an inflated damage award.

This Court's prior decisions have never required that a notice of a class action settlement must anticipate and spell out every possible implication and interpretation of each material term of a class action settlement agreement. It has been widely understood instead that the function of a class notice is to *summarize* the principal terms of the agreement.[10] The interpretation and construction of those terms is left for later decision as disputes arise, based on basic principles of contract law.[11] The Settlement here is enormously

10. *See, e.g.*, Herbert B. Newburg & Alba Conte, NEWBURG ON CLASS ACTIONS § 11.53 (3d ed. 1992) ("Rule 23(e) notice is designed to be only a summary of the litigation and the settlement and it is crucial to apprize class members of the right and opportunity to inspect the complete settlement documents, papers, and pleadings filed in the litigation. The notice need not be unduly specific.").

11. *See, e.g.*, *In re Holocaust Victim Assets Litig.*, 282 F.3d 103, 108 (2d Cir. 2002) (contract principles to be applied to determine scope of release in class action settlement); *In re Airline Ticket Comm'n Antitrust Litig.*, 268 F.3d 619, 623-25 (8th Cir. 2001) (contract principles applied to determine scope of settlement class).

complicated. It covers many issues, not only those addressing IOOs. If it were necessary, to ensure the ability later to obtain enforcement injunctions, to explain in detail in the notice all possible implications and interpretations of each significant provision, class notices would become overwhelmingly complex and difficult to understand. Yet only recently this Court approved an amendment to the Federal Rules of Civil Procedure requiring class action notices to be "concisely" stated. *See* FED. R. CIV. P. 23(c)(2)(B) (as effective Dec. 1, 2003).

CONCLUSION

For all these reasons, the Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

ROBERT D. ROSENBAUM
JEROME I. CHAPMAN
SARAH M. BRACKNEY
RICHARD KORNYLAK
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
(202) 942-5862

PETER L. ZIMROTH
Counsel of Record
ARNOLD & PORTER LLP
399 Park Avenue
New York, NY 10022
(212) 715-1010

Counsel for Petitioner

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT DATED MAY 25, 2004

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Nos. 02-4582, 03-2033,
03-2936, and 03-4362

(02-4582)

IN RE: DIET DRUGS
(PHENTERMINE/FENFLURAMINE/
DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

Linda Smart, a class member who has exercised her intermediate opt-out rights

Appellant

(03-2033)

IN RE: DIET DRUGS
(PHENTERMINE/FENFLURAMINE/
DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

Clara Clark, Linda Smart, George M. Fleming, Fleming & Associates, L.L.P., Mike O'Brien and Michael C. Abbott,

Appellants

Appendix A

(03-2936)

IN RE: DIET DRUGS
(PHENTERMINE/FENFLURAMINE/
DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

Keith K. Barlow, Ruby S. Barlow, Cherry Barnes, Joe Wayne Burton, Nora K. Burton, Lonelle S. James, Michael J. Miller, Kenneth W. Smith, Miller & Associates, Edward A. Williamson, Fenton B. DeWeese, II, The Law Office of Edward A. Williamson, Merrida Coxwell, Charles R. Mullins, Coxwell & Associates, PLLC, and Eugene C. Tullos,

Appellants

(03-4362)

IN RE: DIET DRUGS
(PHENTERMINE/FENFLURAMINE/
DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

Linda Eichmiller, Brenda Cook, Richard Cook, Doris Caldwell, Susan McCarty, Jim McCarty, Jr., Julia Campbell, Carolyn Winters, Bobby G. Winters, Macy Houston, and John F. Houston, III,

Appellants.

Appendix A

On Appeal from the United States District Court for the
Eastern District of Pennsylvania
(MDL No. 1203)
District Judge: Honorable Harvey Bartle, III

Argued: December 10, 2003

Before AMBRO, FUENTES and CHERTOFF, Circuit Judges.

(Opinion filed May 25, 2004)

OPINION

Chertoff, *Circuit Judge.*

This appeal arises out of the settlement of a complex multidistrict federal mass tort class action. As part of the complicated settlement agreement, class members were entitled to opt out at various stages. Those who chose to opt out initially were freed to pursue their remedies elsewhere. Those who did not opt out at the beginning were afforded opportunities to opt out "downstream" at an intermediate stage or at the "back-end." But those downstream opt-out rights were not absolute. Rather, members who elected to delay an opt-out beyond the initial stage were informed that they would not have unfettered ability to litigate all claims elsewhere. Instead, among other things, these so-called intermediate and back-end class "opt-outs" were precluded under the settlement agreement from pursuing punitive, exemplary, or multiple damages.

Appendix A

The questions presented here arise from the District Court's efforts to enforce the terms of the settlement against intermediate opt-out class members now litigating their claims in various state courts. What appellee class counsel and appellee defendant fear is that counsel for intermediate opt-outs will undermine the efficacy of the settlement by evading or circumventing the punitive damages restrictions to which they are bound under the agreement. Appellants, who are individual intermediate opt-outs now pressing claims in state court, complain that the District Court has gone beyond enforcing the plain restrictions of the settlement and has taken steps that will hamper or defeat plaintiffs' ability to pursue claims that are not barred by the settlement.

In one sense, the issues framed in the appeal reflect efforts by creative counsel on both sides to interpret and apply settlement terms so as to gain advantage in the individual lawsuits brought by intermediate opt-outs in various state courts. But larger institutional and fairness issues are at stake.

The nationwide class settlement is a device that holds the promise of resolving millions of claims in a way that affords deserving claimants some measure of relief while preserving a defendant business as a viable entity that can actually pay compensation. *See In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prods. Liab. Litig.*, 55 F.3d 768, 784 (3d Cir.1995). All claimants benefit from such an outcome, because each has a fair opportunity at recovery. Later claimants need not fear that the fund will be exhausted before their turn comes, or that the defendant will undertake a scorched earth defense that consumes assets otherwise available for compensation, or simply turn off the spigot by

filing for bankruptcy. The defendant, too, obviously benefits from a limit to liability that ensures corporate survival. For this type of global settlement to work, however, the district court must successfully discharge the herculean task of enforcing the terms of the class settlement agreement against the constant pressure of some settlement class members who, having obtained part of a loaf through the agreement, now pursue alternative avenues to obtain additional slices. Otherwise, individual class members' activities "would be disruptive to the district court's ongoing settlement management and would jeopardize the settlement's fruition." *Carlough v. Amchem Prods., Inc.*, 10 F.3d 189, 204 (3d Cir.1993).

As appealing as the efficiencies of a nationwide mass tort class settlement may be, however, the Supreme Court has repeatedly cautioned that they cannot override fundamental principles of due process or faithful application of controlling law. *See Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 845-48 (1999); *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 620 (1997); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 812 (1985). Because a class settlement disposes of the rights of many people who are absent from the proceeding and only virtually represented by class counsel, due process considerations such as adequacy of notice and adequacy of representation have special force. *Ortiz*, 527 U.S. at 847-48. As we observed in our opinion in *Georgine v. Amchem Prods., Inc.*-in a passage endorsed by the Supreme Court, *see* 521 U.S. at 628—inadequacies in the quality of notice raise "serious fairness concerns." 83 F.3d 610, 634 (3d Cir.1996).

Moreover, when a federal court seeks to effectuate a settlement agreement by way of enjoining state court proceedings, additional constraints qualify its authority. We have held that district courts have the authority under the All Writs Act, 28 U.S.C. § 1651, to protect their jurisdiction by enjoining state court proceedings that interfere with a judicially approved settlement. *See In re Prudential Ins. Co. Sales Practices Litig.*, 314 F.3d 99, 103-05 (3d Cir.2002) (hereinafter *Prudential II*); *In re Diet Drugs Prods. Liab. Litig.*, 282 F.3d 220, 233-39 (3d Cir.2002) (hereinafter *Diet Drugs I*). But the Anti-Injunction Act, 28 U.S.C. § 2283, and federalism concerns circumscribe this power and require that it be "construed narrowly" and invoked sparingly. *Diet Drugs I,* 282 F.3d at 233-34. The power of federal courts to intrude into the domain of state courts administrating their own laws implicates a host of sensitive concerns and is therefore limited. *See, e.g., Rizzo v. Goode,* 423 U.S. 362, 379-80 (1976); *Huffman v. Pursue, Ltd.*, 420 U.S. 592, 600-01 (1975).

In addition, as with any injunction, traditional principles of equity apply. The terms of any injunction, for example, must be commensurate with the violation the court seeks to remedy. And practical considerations such as manageability and enforceability militate against an order that enmeshes a district court in protracted micromanagement of litigation in a state court. These principles of equity counseling restraint take on particular significance when issues of federalism are involved. When federal courts are confronted with requests for relief that require interference with state civil functions, "they should abide by standards of restraint that go well beyond those of private equity jurisprudence." *Huffman,* 420 U.S. at 603.

All of these concerns come to bear on our resolution of the appeal from the District Court's orders in this case. For the reasons stated in this opinion, we agree that the District Court had power under the All Writs Act to supervise and curtail the actions of intermediate opt-out class members in pursuing their individual claims. But we believe that the injunctions imposed some restrictions not fairly comprehended within the terms of the settlement agreement and class notice and, in certain ways, transgressed the limits of federalism and prudence that confine the exercise of federal judicial authority.

Emphatically, the District Court is empowered to protect its jurisdiction and effectuate the settlement agreement. In this case, however, elements of the protective orders in question must be refashioned to be consistent with fair class notice, to respect appropriate boundaries in relation to state courts, and to accord with traditional principles of equity jurisprudence.

I.

A.

The history of this litigation was previously detailed in our opinion in *Diet Drugs I,* 282 F.3d at 225-29. The cases marshaled before the District Court arose from the marketing of two appetite suppressants, fenfluramine (sold as "Pondimin") and dexfenfluramine (sold as "Redux"). Appellee American Home Products[1] removed the drugs from

1. American Home Products changed its name to Wyeth in March of 2002. We use the name Wyeth for the remainder of the opinion.

the market in September of 1997, after data came to light suggesting a link between use of the drugs and valvular heart damage ("VHD") and after the United States Food and Drug Administration ("FDA") issued a public health advisory alert. By that time, four million people had taken Pondimin over the previous two years, and two million people had taken Redux.

Following the FDA's issuance of the public health warning and Wyeth's withdrawal of the diet drugs from the market, approximately eighteen thousand individual lawsuits and over one hundred putative class actions were filed in federal and state courts around the country. Most plaintiffs alleged that the drugs caused them to suffer from VHD. A small fraction claimed the drugs caused them to suffer from primary pulmonary hypertension ("PPH," a rare and often fatal lung disease), neurotoxic injuries, or other assorted injuries. In December of 1997, the Judicial Panel for Multidistrict Litigation transferred all the federal actions to Judge Louis Bechtle in the United States District Court for the Eastern District of Pennsylvania, creating Multidistrict Litigation 1203 ("MDL 1203").[2]

In April of 1999, Wyeth began "global" settlement talks with plaintiffs in the federal action together with several plaintiffs in similar state class actions. The parties reached a tentative settlement agreement for a nationwide class in November of 1999. Soon thereafter, on November 23, 1999, the District Court conditionally certified a nationwide

2. Judge Bechtle has since retired, and Judge Harvey Bartle, III, now presides over MDL 1203.

settlement class and, concurrently, preliminarily approved the settlement.

The Court scheduled a fairness hearing for May 1, 2000 on class certification and final settlement approval. On August 28, 2000, the District Court entered a final order certifying the class and approving the settlement.

B.

The settlement agreement embraces all persons who took Pondimin or Redux. Wyeth undertook to pay up to $3.75 billion (present value) to fund benefits to members of the class. Settling class members agreed in return to release Wyeth from all claims arising out of their ingestion of the drugs, other than claims based on PPH brought by individuals who met certain medical criteria.

The agreement was crafted to avoid an all-or-nothing choice at the threshold. Rather, several opt-out points were envisioned at various places along the continuum of the settlement period. Putative class members who wished to opt out entirely from the settlement, foregoing all benefits and any restrictions, were obliged to file their opt-out notices by March 30, 2000. Drug users who chose not to opt out initially became settlement class members, bound not to assert "settled claims" against Wyeth except as the agreement permits.[3]

---

3. "Settled claims" generally included all conceivable claims arising out of purchase and use of the diet drugs but specifically excluded, among other things, claims based on PPH.

Appendix A

The agreement allows class members who are medically and otherwise eligible opportunities to opt out at a later time, at an intermediate stage.[4] Those who choose to opt out at an intermediate stage receive no compensation but are permitted to pursue most of their "settled claims" individually, subject to certain restrictions. The settlement agreement provides, in relevant part:

> [Intermediate opt-outs] may not seek punitive, exemplary, or any multiple damages against [Wyeth and other released parties]; . . . . [Intermediate opt-outs] may not use any previous verdicts or judgments against [Wyeth], or factual findings necessary to such verdicts or judgments, for purposes of establishing claims or facts in order to obtain a verdict or judgment. . . . Nor may [an intermediate opt-out] . . . seek to introduce into evidence against [Wyeth], for any purpose, such a verdict, judgment or factual finding.

Joint App. 616-17.

In return for intermediate opt-outs' acceptance of the limitation on punitive and multiple damages, Wyeth agreed not to assert any statute of limitations, laches, or claims-splitting defenses against allowed individual claims.

---

4. Some class members who did not exercise an intermediate opt-out reserved a so-called "back-end" opt-out right. Back-end opt-out rights are not at issue in this appeal.

In approving the settlement, the District Court expressly relied in part on the finding that "class members had an opportunity to preserve their punitive damages claims by exercising the initial opt out." *In re Diet Drugs Prods. Liab. Litig.*, No. 99-20593 2000 WL 1222042, at *49 n. 22 (E.D.Pa. Aug.28, 2000) ("Memorandum and Pretrial Order No. 1415," hereinafter "PTO 1415"). The District Court also observed that the waiver of punitive damages was not an inappropriate "trade-off," since "punitive damage claims are often illusory" and subject to judicial limitation or reduction as a matter of fairness to the defendant. *Id.* In addition, the District Court expressly retained jurisdiction to "enforce the Settlement in accordance with its terms; . . . and to enter such other and further orders as are needed to effectuate the terms of the Settlement." *Id.* at *72.

This Court affirmed PTO 1415 without opinion. *In re Diet Drugs Prods. Liab. Litig.*, 275 F.3d 34 (3d Cir.2001).

C.

A number of class members who did not exercise their initial opt-out rights elected to opt out at the intermediate stage. Plaintiffs Clara Clark and Linda Smart, both represented by the Texas law firm of Fleming & Associates, filed lawsuits in Texas state court. Clark sued Wyeth and her physician in 2002, alleging claims of negligence, products liability, improper warnings, and fraud. Clark's final amended petition seeks recovery of compensatory damages, including damages for pain, disfigurement, mental anguish, and medical expenses. Likewise, Smart's petition alleges claims against

Wyeth and her physician for actual damages for pain, disfigurement, anguish, and medical expenses arising from state tort claims of negligence, failure to warn, and design defect.

Meanwhile, in state court in Mississippi, class member Lonelle James, and others, also filed claims against Wyeth after exercising their intermediate opt-out rights. James was selected as the first trial plaintiff. Her claims were based on state law theories of negligence, strict liability for design and marketing defect, inadequate and improper warnings, misrepresentation, and breach of implied warranty. James sought compensatory damages—including damages for pain and mental anguish, lost earnings, disfigurement, physical impairment, medical expenses, and loss of enjoyment of life—from both Wyeth and her physician.

Plaintiffs' state court claims were pleaded in terms that appeared to abide by the terms of the settlement preclusion of punitive and multiple damages. But the actual conduct of the litigation raised justifiable fear in the District Court, and among the counsel for defendant and the class, that the plaintiffs were seeking to obtain through the back door what they were barred from receiving through the front. Reviewing the state court submissions by Clark's counsel, the District Court found-and this is undisputed- that Clark's case summary was "replete with statements leading ineluctably to the conclusion that such punitive damages are being sought, even though not by that name." *In re Diet Drugs Prods. Liab. Litig.*, No. 99-20593, Memorandum and Pretrial Order No. 2625, at 2 (E.D. Pa. filed October 16, 2002) (hereinafter "PTO 2625"). Clark's case summary expressed

the intent to offer evidence concerning "'tens of thousands of people [who] were injured'"; Wyeth's guilt of "'corporate avarice'"; and its alleged "'goal of increasing profits at the expense of human life.'" *Id.* at 2-3. Worse yet, another submission (in a perhaps Freudian slip) averred that, among other things, "'[p]laintiff seeks punitive damages.'" *Id.* at 4. Before the District Court, Clark's counsel disavowed that claim as an error. The District Court concluded, however, that Clark's counsel was seeking to "circumvent" the punitive damages bar and enjoined him from:

> introducing any evidence or making any statement before or argument to the court or jury related directly or indirectly to (a) punitive, exemplary or multiple damages, however described; and (b) malicious, wanton or other similar conduct of Wyeth, however described; . . . [or] any medical condition of plaintiff caused by Wyeth other than mitral valve regurgitation [VHD] or pulmonary hypertension secondary to mitral valve regurgitation.

Id. at ¶¶ 2-3.

Soon thereafter counsel Fleming's other client, Linda Smart, found her state court case brought to the attention of the District Court. The District Court noted that Fleming was obviously aware of the ruling in the Clark litigation, but nevertheless had submitted a proposed jury charge containing inflammatory language and references to destruction of evidence and a cover up. The District Court rejected the

contention that this evidence was admissible on issues properly before the state trial court and concluded that

> to allow a class member to introduce into evidence or to argue the elements of a punitive damage claim on the condition that he or she does not specifically request punitive damages by name .... would create a giant loophole.

In re Diet Drugs Prods. Liab. Litig., No. 99-20953, Memorandum and Pretrial Order No. 2680, at 7 (E.D. Pa. filed December 11, 2002) (hereinafter "PTO 2680"). Consequently, the Court issued an injunction similar to that in the Clark case.

Only a few weeks later, Wyeth returned to District Court once again to address Clark. Reviewing Clark's amended trial exhibit list, the District Court observed that it demonstrated "counsel's motive to infect the trial with improper bad conduct evidence concerning Wyeth." *In re Diet Drugs Prods. Liab. Litig.*, No. 99-20593, Memorandum and Pretrial Order No. 2717 at 3 (E.D. Pa. filed January 29, 2003) (hereinafter "PTO 2717"). At the same time-and significantly-the District Court quoted the state trial judge, who expressed his commitment to assure "'a fair verdict that is an approximation of the damages and not a result of them [the jury] being incensed.'" *Id.* at 4. The District Court concluded that counsel Fleming had merely withdrawn certain submissions and substituted others in an effort to circumvent the prior injunctions.

The District Court held Fleming in civil contempt and issued an order, PTO 2717, enjoining Clark and her counsel from commencing the state trial until Fleming submitted, and the Court approved, a statement under oath that he would obey PTO 2625. The order provided:

> That statement must declare that with respect to Wyeth's conduct he will not inject into the case any evidence, statement, or argument, directly or indirectly, that connotes more than simple negligence or defective design without fault. The statement must also declare that he will not introduce at the trial any reference to Wyeth's size, financial condition, or worth. He must also include as part of his statement his trial exhibits, witness list, and points for charge . . . .

Id. at ¶ 2.

Back in Texas, the trial judge in the Clark case held an extensive pretrial conference. On February 5, 2003, State District Judge Dennis Powell issued an extensive thirteen-page pretrial order. Judge Powell's carefully reasoned and written opinion exhibited understanding of the effect of the settlement preclusion and a determination to honor it. The State District Judge perceptively observed that "not surprisingly, the plaintiff wants to try the case in a manner that will maximize the chances of a significant recovery, and, not surprisingly, the defendant wants to try the case in a manner that will minimize the chances of a significant recovery." Joint App. 1281. Accordingly, the state court flatly prohibited evidence relevant only to punitive or

exemplary damages and evidence relevant to other issues but unduly prejudicial or misleading. At the same time, Judge Powell said he would

> not require the plaintiff to "try the case in a vacuum of the defendant's design," which could result in the jury improperly speculating about liability issues and evidence (or the lack thereof) and factoring such speculations into causation issues or damage evaluations.

Id. at 1282.

A good deal of the state pretrial order is devoted to analyzing Wyeth's purported willingness to stipulate or concede certain issues so as to remove them from the case. This offer-which was brandished by Wyeth before the federal District Court during the Fleming contempt proceeding that led to PTO 2717-presumably would have eliminated any proper incentive for Clark to offer inflammatory evidence as part of a negligence or design case. But the State District Judge, armed with his understandably greater familiarity with Texas tort law, found Wyeth's apparent concessions to be less than they appeared. As he pointed out, the proposed concessions, which would supposedly leave only causation and damages in the case, would actually do no such thing. In the words of Judge Powell:

> Likewise the defendant created the impression before [U.S. District] Judge Bartle that "they [Wyeth] also admitted that the injury was foreseeable," and that "the injury is foreseeable

> from the defectively designed product." Nonetheless, contrary to the representations to both courts, the [proposed concession] contains no finding that the injury was foreseeable by the defendant, or that the injury was foreseeable from the defectively designed product. The law requires proof, the plaintiff pleaded it, the defendant refused to admit it was conceded, but then the defendant does not want the plaintiff to put on evidence on that element.

Id. at 1288-89.

The state trial court noted an additional problem: the proposed concessions would place the court in a dilemma. If certain issues were taken from the case with no actual admission by Wyeth, it would require the court to instruct the jury that defendant would be automatically liable if the plaintiff's injury were caused by Wyeth's drug, without regard to fault. But this is a matter that could affect jury voir dire, Judge Powell explained, and might require striking potential jurors who could not return a verdict on damages without "considering whether absolute liability law was fair or not." *Id.* at 1290.

For these reasons, Judge Powell declined to accept Wyeth's concessions in their tendered form, although he remained open to a stipulation of outright admission on one or more of the elements of any cause of action. "No doubt some evidence that would be relevant to liability would also be relevant to causation, but this submission would greatly simplify the evidence. . . ." *Id.* at 1291.

Evidently, the parties found this invitation unappealing, and the action moved again to federal court in Philadelphia. In March of 2003, the District Court conducted a lengthy conference and reviewed and ruled on voluminous deposition excerpts and proposed trial exhibits to determine whether the settlement agreement barred Clark from offering them into evidence at trial. The District Court entered an order that enforces a series of prophylactic prohibitions against introducing evidence deemed relevant only to punitive damages or unfairly prejudicial when balanced against probative value.

First, the order forbids plaintiffs from offering into evidence a list of specific exhibits and deposition testimony. And, except as specifically allowed by the accompanying memorandum, it prohibits counsel from "making any statement or argument to the court or jury related directly or indirectly" to the forbidden evidence. The District Court ruled, for example, that Clark (1) could attack the credibility of certain medical review articles by proving they were funded by Wyeth, but not by showing that they were actually ghostwritten at the behest of Wyeth; (2) could not offer any evidence of concealment of information or destruction of documents; (3) must redact portions of documents suggesting problems with Wyeth's diligence in reporting serious side-effects of the drugs to the FDA; and (4) must redact an internal Wyeth memorandum to eliminate the phrase "the public is increasingly concerned and afraid of the drug." *In re Diet Drugs Prods. Liab. Litig.*, No. 20593, Memorandum and Pretrial Order No. 2828 (E.D. Pa. filed April 8, 2003) (hereinafter "PTO 2828").

Appendix A

Second, the order bars Clark and her attorneys from "introducing any evidence, making any statement before or argument to the court or jury, related directly or indirectly to":

> [1] punitive, exemplary or multiple damages, however described;
>
> [2] malicious, wanton or *other similar conduct* of Wyeth, however described;
> . . .
>
> [3] any medical condition of plaintiff caused by Wyeth other than left-sided mitral valve regurgitation or pulmonary hypertension secondary to mitral valve regurgitation;
> . . . .
>
> [4] Wyeth's profits, size or financial condition;
>
> [5] the amount or size of Wyeth's sales of diet drugs or other products;
>
> [6] Wyeth's marketing or promotion of diet drugs to the extent that Wyeth placed marketing or promotion ahead of health or safety concerns;
>
> [7] any deception or any destruction, hiding, overwriting, or deliberate miscoding of documents or information by Wyeth;

> [8] any involvement by Wyeth in the ghostwriting of articles;
>
> [9] primary pulmonary hypertension;
>
> [10] neurotoxicity; and
>
> [11] any other disease, illness or condition or persons suffering from any other disease, illness or condition caused by Redux or Pondimin except for left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease.

Id. at 1-3 (emphasis added). So, for example, the District Court allowed Clark to prove that relevant warnings were inadequate or wrong but said Clark "may not prove or argue that any such failure was deliberate or intentional." *Id.* at 9.

The District Court vacated its previous orders, PTO 2625 and PTO 2717, in light of the more recent and comprehensive PTO 2828. And, on June 10, 2003, the District Court issued Pretrial Order 2883 ("PTO 2883"), which essentially incorporated the restrictions of PTO 2828 and enforced them against plaintiff James in her case in Mississippi state court. Appellants timely appealed PTO 2680 (Smart), PTO 2828 (Clark), and PTO 2883 (James).

In October of 2003, while those appeals were pending, Wyeth returned to federal court seeking an injunction against other intermediate opt-outs-including Linda Eichmiller, also represented by Fleming & Associates-pursuing claims in

Georgia and Mississippi state courts. Wyeth argued that counsel from Fleming & Associates were seeking to introduce evidence in violation of PTO 2828 even though they had agreed to comply with PTO 2828 in other cases pending our review of the order on appeal.

Wyeth asserted that counsel sought to introduce evidence regarding PPH-specifically, a label for Pondimin noting that some users had suffered from PPH and a "black box warning" regarding PPH that the FDA was considering in connection with the approval of Redux-even though plaintiffs were only claiming they suffered from VHD. The District Court entered an injunction similar to PTO 2828, Pretrial Order 3088 ("PTO 3088"), and explicitly barred plaintiffs from seeking to introduce the PPH evidence at trial.

Plaintiffs timely appealed PTO 3088, and it was consolidated by orders of this Court with the other appeals from the District Court's earlier similar orders. We have jurisdiction under 28 U.S.C. § 1292(a)(1).

II.

A distasteful picture of the state court litigation emerges, displaying what some might consider the excesses of our adversary justice system. Each side sought to manipulate the settlement agreement in order to optimize its advantage. Wyeth's counsel resisted admitting, and sought to exclude, evidence that tended to support any liability by Wyeth. Plaintiffs' counsel, notably Fleming, repeatedly skirted the settlement and the District Court's orders, plainly seeking to inject prejudicial matter into the state court cases, including

information about Wyeth's profits and sales that was clearly irrelevant to negligence liability, causation, or compensatory damages, and that could only be relevant to obtaining punitive damages.

The District Court properly observed that, were plaintiffs' counsel permitted to flout the limits of the settlement, the

> floodgates will be open and the prohibition against punitive damages in the court approved Settlement Agreement will be nothing but a dead letter, with potentially dire consequences for the settlement as a whole.

PTO 2717. Faced with this prospect, the District Court entered the injunctions at issue in this appeal in order to protect the settlement against guerrilla warfare from the opt-out lawyers.

Appellants now urge us to vacate the District Court's orders for three primary reasons. First, they argue that the orders run afoul of the Anti-Injunction Act and All Writs Act. Second, they contend that the *Younger* abstention doctrine required the District Court to refrain from enjoining the state court proceedings. Finally, appellants argue that the orders contravene the terms of the settlement agreement, are unmanageable, and run afoul of principles of federalism and comity.

"The standard of review for the authority to issue an injunction under the Anti-Injunction Act and the All-Writs Act is de novo." *In re Prudential Ins. Co. of Am. Sales*

Practices Litig., 261 F.3d 355, 363 (3d Cir.2001) (internal citations omitted) (hereinafter *Prudential I*). When reviewing a district court's decision whether to abstain, "the underlying legal questions are subject to plenary review, but the decision to abstain is reviewed for an abuse of discretion." *Grode v. Mut. Fire, Marine & Inland Ins. Co.*, 8 F.3d 953, 957 (3d Cir.1993). "We review the terms of an injunction for an abuse of discretion, underlying questions of law receive de novo review, and factual determinations are reviewed for clear error." *Prudential I*, 261 F.3d at 363. Finally, we apply plenary review to a district court's construction of a settlement agreement, but we review a district court's interpretation of a settlement agreement for clear error. *Coltec Indus., Inc. v. Hobgood*, 280 F.3d 262, 269 (3d Cir.2002) (citing *In re Cendant Corp. Prides Litig.*, 233 F.3d 188, 193 (3d Cir.2000)).[5]

A.

The All Writs Act empowers district courts to "issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law." 28 U.S.C. § 1651. The authority the All Writs Act imparts to district courts is limited, however, by the Anti-Injunction Act, which prohibits injunctions "to stay proceedings in a State court except as expressly authorized by Act of Congress, or where necessary in aid of its jurisdiction, or to protect or effectuate its judgments." 28 U.S.C. § 2283.

---

5. We discussed at length the distinction between contract construction and contract interpretation in *Ram Constr. Co. v. Am. States Ins. Co.*, 749 F.2d 1049, 1053 (3d Cir.1984).

The two statutes act in concert, and "[i]f an injunction falls within one of [the Anti-Injunction Act's] three exceptions, the All-Writs Act provides the positive authority for federal courts to issue injunctions of state court proceedings." *In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prods. Liab. Litig.*, 134 F.3d 133, 143 (3d Cir.1998); *see also Carlough*, 10 F.3d at 201 n. 9. The pretrial injunctions at issue here were not expressly authorized by statute, so they may be justified only under the Anti-Injunction Act's "in aid of its jurisdiction" or "protect or effectuate its judgments" exceptions. These exceptions "are narrow and are 'not [to] be enlarged by loose statutory construction.' " *Chick Kam Choo v. Exxon Corp.*, 486 U.S. 140, 146 (1988) (quoting *Atl. Coast Line R.R. v. Bhd. Of Locomotive Eng'rs*, 398 U.S. 281, 287 (1970)).

The "protect or effectuate its judgments" exception, known as the "relitigation exception," is "founded in the well-recognized concepts of *res judicata* and collateral estoppel." *Id.* at 147. "The relitigation exception was designed to permit a federal court to prevent state litigation of an issue that previously was presented to and decided by the federal court." *Id.*

We approved an injunction against state court proceedings under the relitigation exception in *Prudential I.* That case arose from the class settlement of claims brought by Prudential policyholders arising from allegedly fraudulent sales practices. Class members were free to choose settlement for some policies and not for others. The notice of settlement specifically advised each potential class member, however, that acceptance of the settlement would prevent any future

assertion of claims that had been or could have been asserted with respect to any policy for which the class member chose to settle.

Two class members accepted the settlement for several policies but opted out for two others. They then brought a Florida state action to recover on the two excluded policies, basing their claims in part on facts that also supported claims arising from settled policies. In effect, plaintiffs sought to undermine the settlement's claim preclusion order.

The District Court enjoined the plaintiffs in the Florida action from "using evidence common to the purchase and sale" of the settled policies. 261 F.3d at 368. The injunction effectuated the settlement agreement's bar against new claims based on "facts and circumstances underlying" the claims that had been settled and released. *Id.* at 361. The order was designed to prevent new claims that were based in whole or part on settled and released claims. The straightforward injunction language mirrored the familiar rules of claim and issue preclusion that are often applied by courts.

This case differs from *Prudential I,* because under the settlement agreement opt-outs' settled claims do not go to judgment; rather, their claims proceed in state courts with limits on the type of damages they can seek. Thus the District Court had to enforce a damages preclusion, not a claim preclusion. This was obviously more complicated because permitted claims could give rise to both allowable compensatory damages and forbidden punitive damages.

Consequently, the concepts of issue and claim preclusion are not entirely apposite here. We need not determine whether the District Court had the authority to effectuate the settlement agreement's punitive damages provision under the Anti-Injunction Act's relitigation exception, however, because in any case it had the power to issue the injunction under the "in aid of jurisdiction" exception.

"[A]n injunction is necessary in aid of a court's jurisdiction only if 'some federal injunctive relief may be necessary to prevent a state court from so interfering with a federal court's consideration or disposition of a case as to seriously impair the federal court's flexibility and authority to decide that case.'" *Diet Drugs I,* 282 F.3d at 234 (quoting *Atl. Coast Line R.R.,* 398 U.S. at 294). One instance where we have determined that a federal court may enjoin state court proceedings to protect its jurisdiction is when a federal court is "entertaining complex litigation, especially when it involves a substantial class of persons from multiple states, or represents a consolidation of cases from multiple districts." *Id.* at 235 (citing *Carlough,* 10 F.3d at 202-04); *see also In re Gen. Motors,* 134 F.3d at 145.

Here, as in *Prudential II,* the District Court retained "continuing and exclusive jurisdiction . . . to administer, supervise, interpret and enforce the Settlement in accordance with its terms." Joint App. 398. In *Prudential II,* we explained:

> The settlement here represented a herculean effort to provide a fair and consistent framework for the resolution of millions of claims. The

> comprehensive procedures implemented for this purpose were integral to this effort. Permitting continued litigation of these claims would "unsettle" what had been thought to be settled, and would disrupt carefully constructed procedures for individual dispute resolution. Allowing comprehensive settlements to be undermined in this way would undeniably deter similar settlements in the future.

314 F.3d at 105; *see also United States v. Alpine Land & Reservoir Co.*, 174 F.3d 1007, 1015 (9th Cir.1999) (finding that the "in aid of its jurisdiction" exception applies when district court retains jurisdiction over a settlement agreement).

As we have described above, the punitive damages release is a central pillar of the settlement agreement. Allowing state court actions to run afoul of that provision would fatally subvert it and render the agreement (and the Court's jurisdiction) nugatory. The District Court's ability to give effect to that provision is necessary in aid of its jurisdiction.

Yet "the fact that an injunction *may* issue under the Anti-Injunction Act does not mean that it *must* issue." *Chick Kam Choo,* 486 U.S. at 151. Specifically, principles of comity, federalism, and equity always restrain federal courts' ability to enjoin state court proceedings. *See Mitchum v. Foster,* 407 U.S. 225, 243 (1972); 17 Charles A. Wright & Arthur R.

Miller, *Federal Practice and Procedure* § 4226, at 551 (2d ed.1995).[6]

B.

Any court determining whether to issue an injunction must consider several factors that guide and constrain its equitable authority. *See Temple Univ. v. White,* 941 F.2d 201, 214-15 (3d Cir.1991); *Shields v. Zuccarini,* 254 F.3d 476, 482 (3d Cir.2001). Of primary importance, a party seeking an injunction must show that there is some legal transgression that an injunction would remedy.[7]

---

6. Appellants raise the issue of *Younger* abstention, the prudential corollary to the Anti-Injunction Act's statutory circumscription of federal courts' ability to enjoin state court proceedings, *see Younger v. Harris,* 401 U.S. 37 (1971), but we need address it only briefly. Although *Younger*'s application to civil proceedings between two private parties remains relatively unclear, a consistent prerequisite is that "an important state interest is implicated." *See Anthony v. Council,* 316 F.3d 412, 418 (3d Cir.2003). We discern nothing about the state civil proceedings at issue here-personal injury suits sounding largely in state tort law-that can fairly be thought to implicate "important state interests." The instances where the Supreme Court and this Court have applied *Younger* to state civil proceedings-such as state contempt proceedings, *Juidice v. Vail,* 430 U.S. 327 (1977); judicial proceedings enforcing state court orders, *Pennzoil Co. v. Texaco, Inc.,* 481 U.S. 1 (1987); and child support contempt proceedings, *Anthony,* 316 F.3d at 421-involved proceedings qualitatively different from those at issue here. This much was inherent in our decision in *Prudential I* and *Prudential II,* where we upheld orders enjoining state tort proceedings.

7. Put differently, a party seeking a permanent injunction must "succeed on the merits." *See, e.g., Temple Univ.,* 941 F.2d at 215.

In addition, any injunction a court issues must be commensurate with the wrong it is crafted to remedy-it is a "settled rule that in federal equity cases 'the nature of the violation determines the scope of the remedy.'" *Rizzo,* 423 U.S. at 378 (quoting *Swann v. Charlotte-Mecklenburg Bd. of Educ.,* 402 U.S. 1, 16 (1971)); *see also Forschner Group, Inc. v. Arrow Trading Co.,* 124 F.3d 402, 406 (2d Cir.1997) ("It is well-settled that the essence of equity jurisdiction has been the power to grant relief no broader than necessary to cure the effects of the harm caused by the violation"). As this Court stated in *Temple Univ. v. White,*

> While the scope of a district court's equitable powers to effect a remedy is broad, the relief which a district court may grant can be no broader than that necessary to correct the violation. Indeed, a federal court is required to tailor the scope of its remedy in order to fit the nature of the violation which it has found.

941 F.2d at 215. The proper tailoring of injunctive relief is especially important when principles of federalism are involved. *See Rizzo,* 423 U.S. at 371 ("[A]ppropriate consideration must be given to principles of federalism in determining the availability and scope of equitable relief."). In other words, "federal courts should always seek to minimize interference with legitimate state activities in tailoring remedies." *Stone v. City and County of San Francisco,* 968 F.2d 850, 861 (9th Cir.1992).

Here, the putative transgression that Wyeth sought to remedy through an injunction was appellants' violation of

the settlement agreement. Thus, two interrelated considerations guide our review: (1) the proper construction of the settlement agreement's punitive damages provision; and (2) the scope of the District Court's injunctions. In other words, we must construe the settlement agreement and then determine the extent to which the District Court's injunctions prohibited actions that contravened the terms of the settlement. An over-inclusive injunction would run afoul of well-established principles of equity and federalism.

1.

The decision of a potential settlement class member to remain with the class or to opt out entirely at the threshold is a fateful one. The average class member has had no hand in negotiating the terms of the settlement. As demonstrated in *Prudential I,* the settlement's preclusive effect may be broad and strict. By waiving an initial opt-out, the class member surrenders what may be valuable rights, in return for countervailing benefits. In this case, important information for these potential class members included the availability, benefits, and disadvantage of the intermediate opt-out right.

This opt-out choice raises a significant issue of fairness. As in *Georgine v. Amchem Prods.*, the individual class members here have claims "that frequently receive huge awards in the tort system." 83 F.3d at 633. They can hardly knowingly waive some of their tort rights without a clear notice of what they are waiving. They may be entirely dependent on the class notice for this information. That is why we paid careful attention to the language of the class notice, which detailed the extent of the released claims, in

upholding the injunction that enforced the preclusive provisions of the settlement in *Prudential I.* 261 F.3d at 366-67.

It follows that the preclusion language in the Diet Drugs class notice and settlement agreement must, in order to avoid due process concerns, be strictly construed against those who seek to restrict class members from pursuing individual claims. *Cf. United States v. Albertini,* 472 U.S. 675, 680 (1985) ("Statutes should be construed to avoid constitutional questions. . . ."). Here, the following language in the class notice informed putative class members of the consequences if they signed onto the class and exercised intermediate opt-out rights:

> If you exercise the Intermediate Opt-Out right, you give up the right to receive further benefits under the Settlement Agreement, but you may choose to pursue in court any legal claims you may have against [Wyeth] relating to your use of Pondimin and/or Redux. However, *it is important to understand that if you exercise the Intermediate Opt-Out right, and choose to bring a lawsuit against [Wyeth], your lawsuit will be subject to certain restrictions including the following:*
>
> • If you exercise your Intermediate Opt-Out right and choose to bring a lawsuit against [Wyeth], you may not seek punitive or multiple damages.
>
> • If you exercise your Intermediate Opt-Out right and choose to bring a lawsuit against [Wyeth], you

> may only assert a legal claim based on the heart valve condition of the relevant Diet Drug Recipient that was [properly diagnosed within a prescribed time period].
>
> • If you exercise your Intermediate Opt-Out right and choose to bring a lawsuit against [Wyeth], both you and [Wyeth] will be subject to certain additional restrictions that are described in the Settlement Agreement. In order for [Wyeth] to be subject to these restrictions, such as waiver of any statute of limitations defense, you must bring your lawsuit, if you choose to do so, within one (1) year from the date on which you exercise your Intermediate Opt-Out right.

Wyeth Br., Ex. A at 12. The corresponding preclusive language in the settlement agreement regarding intermediate opt-outs appeared in three portions:

> [1] [An intermediate opt-out] may pursue all of his or her Settled Claims (except for those claims set forth in subparagraphs (e) and (g) of Section I.53[8]), against [Wyeth and other released parties],

---

8. Subparagraphs (e) and (g) of Section I.53 include, as part of the definition of "Settled Claims," all claims for damages or any other remedies for:

> e. consumer fraud, refunds, unfair business practices, deceptive trade practices, Unfair and Deceptive Acts and Practices ("UDAP"), and other similar claims whether arising under statute, regulation, or judicial decision;

(Cont'd)

but may only assert a claim . . . based on the heart valve of the relevant Diet Drug Recipient which was diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram. . . .

[2] With respect to [any intermediate opt-out] who initiates a lawsuit against any of the Released Parties within one year from the date on which the Intermediate Opt-Out right is exercised, [Wyeth] shall not assert any defense based on any statute of limitations or repose, the doctrine of laches, any other defense predicated on the failure to timely pursue the claim, any defense based on "splitting" a cause of action, any defense based on any release signed pursuant to the Settlement Agreement, and/or any other defense based on the existence of the Settlement Agreement, except to the extent provided herein. [Intermediate opt-outs] may not seek punitive, exemplary, or any multiple damages against [Wyeth or other released parties]. . . .

[3] [Intermediate opt-outs] may not use any previous verdicts or judgments against [Wyeth], or factual findings necessary to such verdicts or judgments, for purposes of establishing claims or

---

(Cont'd)

. . .

g. medical screening and monitoring, injunctive and declaratory relief[.]

Joint App. 572.

> facts in order to obtain a verdict or judgment against [Wyeth] under the doctrines of res judicata, collateral estoppel or other doctrines of claim or issue preclusion. Nor may [intermediate opt-outs] seek to introduce into evidence against [Wyeth], for any purpose, such a verdict, judgment, or factual finding. Lawsuits initiated by [intermediate opt-outs] shall be subject to the provisions of Section VII.F.3.[9]

Joint App. 615-17.

Three restrictions emerge. First, the potential class members were told that intermediate opt-outs will be allowed to "pursue all . . . Settled Claims" for timely diagnosed VHD, except for those pertaining to consumer fraud or business loss. Specifically included are claims for such open-textured

---

9. Section VIII.F.3 provides:

> The Parties to the Settlement . . . shall not seek to introduce and/or offer the terms of the Settlement Agreement, any statement, transaction or proceeding in connection with the negotiation, execution or implementation of this Settlement Agreement, any statements in the notice documents appended to this Settlement Agreement, stipulations, agreements, or admissions made or entered into in connection with the fairness hearing or any finding of fact or conclusion of law made by the Trial Court, or otherwise rely on the terms of this Settlement, in any judicial proceeding, except insofar as it is necessary to enforce the terms of the Settlement.

Joint App. 704.

injuries as mental anguish, pain and suffering, and loss of consortium. Second, Wyeth agreed not to assert any defenses based on class members' failure to assert a timely claim and class members "may not seek punitive, exemplary, or any multiple damages." Finally, the provision addressed certain evidentiary restrictions: (1) intermediate opt-outs may not "seek to introduce into evidence" earlier verdicts or judgments against Wyeth, or the factual findings underlying them; and (2) neither party can offer evidence regarding the settlement agreement, including evidence regarding its negotiation or implementation.

The plain language is telling. The intermediate opt-out provision comprehensively promised that claims for a wide variety of losses can be sought, so long as they are for FDA-positive VHD. There is no limitation on VHD-related claims or causes of action. Moreover, there is no expression that opportunities to recover for mental anguish, pain, or loss of consortium will be impeded or hampered. If the drafters were concerned these type of recoveries might become vehicles for sub rosa punitive awards, they might have limited them; they did not.

Instead, the authors of the settlement specifically excluded only "punitive, multiple, and exemplary damages" from the laundry list of allowable recoveries. This reinforces the natural conclusion that claims for VHD were not restricted by the settlement, so long as forms of damages other than those expressly forbidden were sought.

Significantly, evidentiary restrictions are explicitly addressed in the relevant provision of the agreement. The

agreement forbids prior adverse findings or judgments against Wyeth from being placed in evidence for any purpose, as well as a wide range of evidence regarding the settlement agreement itself. This implies to the reader of the agreement that the drafters knew how to identify evidence restrictions when they wished to do so. There is no restriction, however, placed on the use of evidence simply because it would be relevant in supporting punitive damages. One deduces from the absence of such an evidentiary restriction that the agreement meant only to block the specified type of damages award and not types of evidence that are relevant to permissible awards but might also be relevant to punitive damages.

Appellees seek to rebut this language by referring to colloquy during the fairness proceedings that they claim further refines the meaning of the punitive damages preclusion. At an October 2002 status hearing, one negotiator stated his understanding that

> the essence of this bargain was that there would be no punitive damages in these downstream opt out cases and that does not simply mean no punitive damages. What [Wyeth] was bargaining for, clearly, they were saying . . . we were willing to pay for what juries determine were caused by our diet drugs without reference to some additional element that is awarded by reference to fault evidence.

Joint App. 2149. This might be pertinent in construing the agreement as between parties who actually participated in

the negotiations. *See, e.g., Bohler-Uddeholm Am., Inc. v. Ellwood Group, Inc.*, 247 F.3d 79, 114 (3d Cir.2001). But due process considerations counsel against binding absent potential class members to understandings that were not made express in the class notice or settlement agreement. And we are particularly wary of binding class members through statements made after the settlement was finalized and after they had to choose whether to opt out.

Appellees urge that our decision in *Prudential I* disposes of appellants' claims because they read that decision to hold that "when class members settle and release some of their claims-but preserve other claims from the settlement-that release bars the plaintiffs from offering evidence relating to the released claims in any subsequent trial of the preserved claims." Wyeth Br. 36. But we think that the settlement preclusion in *Prudential I* is different from this one, and different in a meaningful way.

The class notice in *Prudential I* informed class members that, in return for accepting settlements on some policy claims, they would release the defendants

> from any and all causes of actions, claims, damages, equitable, legal and administrative relief, interest, demands or rights, of any kind or nature whatsoever . . . that have been, could have been, may be or could be alleged or asserted now or in the future . . . on the basis of, connected with, arising out of, or related to, in whole or in part, the Released Transactions [i.e., settled policies under the settlement agreement].

261 F.3d at 367 (emphasis omitted). In other words, any *cause of action or claim* that was in any way related to a settled policy-even a claim that "could have been" raised on the basis of such a policy-was barred. This release language was indeed, as the class notice explicitly warned potential class members, "intended to be very broad." *Id.* at 366. And the District Court's injunction in that case tracked the language of the class notice, forbidding class members from bringing a lawsuit "based on or related to the facts and circumstances underlying the claims and causes of action" that were settled in the class action. *Id.* at 361. To block new claims "based on facts" underlying other settled claims is simply to effectuate the class notice language releasing claims that "could have been brought" based on the settled transactions. In other words, the release language in the Prudential settlement was typical general release language that prevents new causes of action from overlapping with settled causes of action with a "common nucleus of operative facts." *Id.* at 367.

Contrast the language in the Diet Drugs release. The Diet Drugs release is not structured as a broad claims preclusion, but as a bar only to the magnitude and type of relief. The only *claims*-based limitations are that (1) the claims must be based on a timely diagnosed VHD injury, and (2) the claim may not be for consumer or business losses. VHD-based claims for compensation, including for pain, anguish, and loss of consortium, are not precluded or limited in any way. Indeed, the settlement agreement specifically contains Wyeth's renunciation of any defense based on "'splitting' a cause of action." What is limited is the type and extent of *damages* for such VHD-claims.

Appendix A

If we were to accept Wyeth's invitation to read this damages limitation as if it were a broad Prudential-type release of all claims that could be the basis for a punitive damages award, we would face an anomaly. Since the predicate to any punitive or multiple damages award is a finding of tortious liability, Wyeth's logic would foreclose opt-out plaintiffs from proving liability at all. That interpretation would make the settlement agreement internally contradictory.

Of course, Wyeth does not press so absurd a contention. But, in effect, Wyeth wants us to read this punitive damages limitation as if it were a limit on the manner in which opt-out plaintiffs can pursue their claims for compensation. Under this view, a plaintiff may show unreasonable behavior to recover compensation for negligence, unless the behavior was really unreasonable (so that it might support punitive damages). Put another way, Wyeth urges that very strong evidence of fault must be diluted so that it would not arouse the jury to award punitive damages, if punitive damages could be awarded-which they cannot be. In the absence of an explicit description of this novel type of restriction in the settlement agreement, we decline to construe the agreement to imply an evidence-dilution requirement for compensation claims that are clearly preserved for the opt-out plaintiffs.

2.

All of this is not to say that the District Court was powerless to restrain opt-out plaintiffs from evading the prohibition against exemplary damages. Even under a strict construction of the settlement agreement, the District Court

was entitled to prevent circumvention of the damages limitation. The District Court acted consistently with the settlement agreement, for example, when it enjoined the introduction of certain types of evidence relevant only to the impermissible purpose of obtaining punitive damages. Appellants conceded this at oral argument. Tr. 9. So, as appellants acknowledged, the District Court correctly banned evidence relating to Wyeth's size, profits, and sales figures, which is not probative of liability, causation, or compensation. *Id.* at 10, 13.

But PTO 2828 swept far more broadly, prohibiting Clark from offering evidence that was relevant-indeed, highly probative-on issues of negligence and failure to warn.[10] The District Court reasoned that such evidence, if suggestive as well of intentional misconduct, fell within the punitive damages bar because it could support a punitive verdict or because it could inflame the state jury. The test that the District Court seemed to employ was to place "off-limits" evidence that was not "necessary" to prove a claim to compensation. PTO 2828, at 8. Excluded under this approach were pieces of evidence that "suggest malfeasance on the part of the company that goes beyond mere negligence," *id.* at 27, or that "connotes more than negligence." *Id.* at 32.

---

10. We center our discussion on PTO 2828 because it was the most comprehensive of the District Court's orders and appears to have established a baseline set of guidelines for all intermediate opt-outs litigating their claims in state courts, regardless of whether they were parties to PTO 2828. Counsel for Eichmiller et al., for example, agreed to comply with PTO 2828 even though it did not specifically bind them.

Appendix A

Intentional or reckless behavior may be highly probative of elements of negligence or defective design cases. The failure to report adverse actions to the FDA-whether accidental or intentional-would be probative of a failure to warn. And intentional or reckless behavior is often relevant to showing conduct below the reasonable standard of care necessary to make out a case of negligence.[11]

---

11. Certain categories of intentional conduct-specifically, intentionally tortious conduct-do not support a claim of negligence in certain jurisdictions. *Compare Dairy Road Partners v. Island Ins. Co.*, 992 P.2d 93, 114-15 (Haw. 2000), *Ins. Co. of N. Am. v. Miller*, 765 A.2d 587, 601 (Md. 2001), *and Jamison v. Encarnacion*, 281 U.S. 635, 641 (1930) *with Landry v. Leonard N. East Ins. Co.*, 720 A.2d 907, 910 (Me.1998), *Am. Nat'l Fire Ins. Co. v. Schuss*, 607 A.2d 418, 423 (Conn. 1992), *and Walters v. Blackshear*, 591 N.E.2d 184, 185 (1992). The distinguishing factor between intentionally and negligently tortious conduct is that an intentional tortfeasor intends to bring about the harm that results from his actions. *See Schuss*, 607 A.2d at 423. Thus even in those jurisdictions where negligence and intentional torts are mutually exclusive, intentional conduct may be relevant to negligence so long as it does not involve intent to bring about the harmful result. *See Landry*, 720 A.2d at 910; Fowler V. Harper et al., *The Law of Torts* § 16.9 n.2 ("An intentional act may be negligent.") (citing *Dartez v. Gadbois*, 541 S.W.2d 502 (Tex.Civ.App.1976)); *see also Ghassemieh v. Schafer*, 447 A.2d 84, 89-90 (Md. Ct. Spec. App. 1982) ("We see no reason why an intentional act that produces unintended consequences cannot be a foundation for a negligence action."); *see also* 57A Am.Jur.2d *Negligence* § 30 (2004). As one major treatise explains:

> [I]ntentional conduct and even intentional risk-taking is analyzed under negligence rules unless the defendant has a purpose to invade the plaintiff's interests or a certainty that such an invasion will occur. . . . The defendant who

(Cont'd)

A few examples suffice to illustrate the problem. The District Court correctly recognized that the use and content of a "black box" on the drug warning label "goes to the issue of failure to warn." *Id.* at 8. Accordingly, it authorized Clark to seek to prove that warnings were "inadequate or wrong and that certain relevant information was not reported or not reported on a timely basis to the FDA." *Id.* at 9. But the Court held that to avoid "implicat[ing]" punitive damages, Clark could not prove that any such failure was intentional. As a consequence, the District Court struck deposition testimony from Wyeth's Associate Director of Safety Surveillance specifically admitting that valvular heart disease reactions to the drugs were not reported to the FDA. *Id.* at 33. The District Court also banned testimony from other witnesses that they fought strenuously against any "black box" warning. PTO 2828, at 31. This evidence certainly tended to prove that the defendant "knows or should know of a potential risk of harm presented by a product but markets

---

(Cont'd)

> intentionally takes a risk may or may not be negligent; negligence will depend upon the seriousness of the risk and the reasons for taking it.
>
> . . . .
>
> In spite of the fact that it is conduct and risk, not mental state that determines negligence, the defendant's state of mind is not necessarily irrelevant in a negligence case. The defendant's knowledge of facts that make a given act risky (as distinct from his attitude) is frequently important on the negligence issue.

Dan B. Dobbs, *The Law of Torts* § 116 (2001).

it without adequately warning of the danger," which is the definition of a "marketing defect" under Texas tort law. *See Sims v. Washex Mach. Corp.*, 932 S.W.2d 559, 562 (Tex. Ct. App. 1995); *see also Jackson v. Johns-Manville Sales Corp.*, 750 F.2d 1314, 1318-20 & n. 8 (5th Cir.1985) (en banc) (Mississippi law). But under PTO 2828, this evidence was placed out of bounds.

Similarly, the District Court placed off-limits any evidence that mentioned medical side-effects other than VHD itself.[12] This evidence was not offered to support claims for these side-effects, since plaintiffs did not suffer from them. Rather, they were offered for other purposes, such as to prove duty to warn. Evidence of the totality of the risks of injury may be admissible under state law to show the scope of the duty to warn, even if the individual plaintiff has not sustained all the injuries in question. *See Dartez v. Fibreboard Corp.*, 765 F.2d 456, 468 (5th Cir.1985). Nevertheless, the District Court ruled out testimony about delays in changing warning labels on Pondimin if the warnings concerned PPH. The Court justified this ruling on the ground that plaintiffs did not have these side-effects, so that this evidence would "have the effect of unfairly arousing the jury against Wyeth." PTO 2828, at 7.

The District Court also categorically prohibited plaintiffs from offering evidence of "Wyeth's marketing or promotion

---

12. This ruling was not based on claim preclusion. Intermediate opt-outs were limited to recovery for VHD but were not barred from recovery for PPH, a side-effect that is distinct from VHD. *See* Joint App. 572-73, 616; PTO 1415, at 70; *In re Diet Drugs*, No. 99-20953, Memorandum and Pretrial Order No. 3065, at 5 (E.D. Pa. filed October 10, 2003).

of diet drugs to the extent that Wyeth placed marketing or promotion ahead of health or safety concerns." *Id.* at 6. The Court took this step on the grounds that "such evidence and argument can have no other purpose than to obtain punitive damages." *Id.* at 20. Evidence tending simply to show that Wyeth wanted to successfully market the diet drugs and make a profit selling them would not be relevant to show, for example, that Wyeth acted negligently. But excessive concern with the image and marketing of the diet drugs at the expense of making efforts toward determining whether they were safe could be probative as to whether Wyeth breached a duty of care towards the plaintiffs.

In effect, the District Court trimmed evidence that was probative, but that it viewed as unnecessary and so inculpatory that it might inflame the jury to award damages that would punish Wyeth instead of simply compensating the plaintiffs. The District Judge effectively adopted the role of a trial judge balancing probative value against unfair prejudice. *Cf.* Fed.R.Evid. 403. By doing that, he moved beyond mere enforcement of the damages restriction, and affected plaintiff's right to try her permissible liability case.

A trial is more than a matter of presenting a series of individual fact questions in arid fashion to a jury. The jury properly weighs fact questions in the context of a coherent picture of the way the world works. A verdict is not merely the sum of individual findings, but the assembly of those findings into that picture of the truth. As the Supreme Court instructed in *Old Chief v. United States,* evidence "has force beyond any linear scheme of reasoning, and as its pieces come together a narrative gains momentum, with power not only

to support conclusions but to sustain the willingness of jurors to draw the inferences, whatever they may be, necessary to reach an honest verdict." 519 U.S. 172, 187 (1997). Unduly sterilizing a party's trial presentation can unfairly hamper her ability to shape a compelling and coherent exposition of the facts.

Of course, at trial this process of evidentiary balancing is nuanced and contextual. For that reason, "excluding evidence under Fed R. Evid. 403 at the pretrial stage is an extreme measure." *Hines v. Consolidated Rail Corp.*, 926 F.2d 262, 274 (3d Cir.1991). In *In re Paoli R.R. Yard PCB Litigation*, we explained:

> [A] court cannot fairly ascertain the potential relevance of evidence for Rule 403 purposes until it has a full record relevant to the putatively objectionable evidence. We believe that Rule 403 is a trial-oriented rule. Precipitous Rule 403 determinations, before the challenging party has had an opportunity to develop the record, are therefore unfair and improper.

916 F.2d 829, 859 (3d Cir.1990) (internal citation omitted). In short, the District Court's broad order prematurely struck the balance between probativeness and prejudice, and did so for trial proceedings yet to occur in another court system before a different judge.

Appellees argue that Clark has no cause to complain about losing access to some evidence relevant to liability because she was offered, and declined, Wyeth's stipulation

not to contest the element of breach of duty. Wyeth Br. 46. Notably, Wyeth did not offer to concede negligence or defective warning before the jury. It proposed, instead, a stipulation, in the form of a conditional double negative, that would present two specific interrogatories to the jury-cause in fact and damages. Joint App. 3371-72.

This parsimonious-indeed, illusory-offer was understandably rejected by Clark's counsel. As State District Judge Powell found, it simply misconceived Texas tort law, and would have created confusion for the jury. But beyond that, restricting plaintiff to a sterile concession and the right to litigate two particularized questions would seriously disadvantage her at trial (as skilled counsel for Wyeth surely recognized). Jurors might well wonder at the fairness of determining causation and damages in a vacuum devoid of any suggestion of liability or negligence. Intermediate opt out plaintiffs never agreed to relinquish their right to try their allowed claims effectively in state court.

Moreover, removing critical issues of fact from the jury without an adequate explanation runs the risk of distorting jury deliberations. The absence of proof that would normally be expected can cause the jury to draw unwarranted inferences. "[T]here lies the need for evidence in all its particularity to satisfy the jurors' expectations about what proper proof should be." *Old Chief,* 519 U.S. at 188. For this reason, unless a stipulation adequately concedes an element of proof, it can prejudice the party carrying the burden of proof. In this case, the proposed concession by Wyeth would, as Judge Powell saw, "raise a substantial

possibility that one or more jurors would be influenced by the lack of evidence and the lack of explanation." Joint App. 1290.

Insofar as the injunctions barred the use of evidence that was relevant to genuine issues in the state trial-apart from punitive, multiple, or exemplary damages-they placed restrictions on opt-out plaintiffs that went beyond the fair terms of the settlement agreement.

3.

Finally, we note that injunctions must be enforceable, workable, and capable of court supervision. *See Lemon v. Kurtzman,* 411 U.S. 192, 200 (1973) ("[E]quitable remedies are a special blend of what is necessary, what is fair, and what is workable."); *United States v. Paramount Pictures, Inc.*, 334 U.S. 131, 161-66 (1948) (vacating injunction that implicated the "judiciary heavily in the details of business management" in order for supervision "to be effective"); *Rutland Marble Co. v. Ripley,* 77 U.S. 339, 358-59 (1870) ("It is manifest that the court cannot superintend the execution of such a decree. It is quite impracticable."); Restatement (Second) of Torts § 943 cmt. a ("In determining the appropriateness of injunctive relief, the court must give consideration to the practicality of drafting and enforcing the order or judgment. If drafting and enforcing are found to be impracticable, the injunction should not be granted."). The District Court's orders raise practical and institutional concerns in this regard.

Appendix A

PTO 2828, as we have seen, is not limited to protecting the core of the settlement's damages limitation by forbidding plaintiffs from seeking such damages in their pleadings or presenting evidence relevant only to such damages. Rather, the order enforces a series of prophylactic prohibitions that affect plaintiffs' ability to obtain permissible compensatory damages. As written, PTO 2828-which is enforceable, of course, by the sanction of contempt-would make it very difficult for plaintiff to try the case that is preserved to her under the settlement agreement.

Numerous exhibits and portions of testimony are excluded definitively, regardless of the purpose for which they are offered. By way of example, the District Court nixed deposition testimony about efforts by Wyeth employees to avoid a "black box" warning. It is not clear what recourse a plaintiff would have if, during the course of trial, a Wyeth employee were to assert that Wyeth was always scrupulous and forthcoming on warning issues. By its terms, the order would appear to forbid plaintiff from offering the deposition testimony for purposes of rebuttal or impeachment. Nor, on the face of the order, would plaintiff be justified in introducing evidence of failure to warn regarding PPH on the ground that it negates the trial testimony that Wyeth is always forthcoming. Normally, a trial judge might well conclude such testimony opened the door for previously out-of-bounds evidence. PTO 2828 does not vest the state judge with that discretion. Presumably, the parties-and the state court-would have to contact the District Court and seek a modification of PTO 2828.

Even more awkward is the broadly framed prohibition against offering evidence "related directly or indirectly" to such topics as wanton or similar conduct by Wyeth, or Wyeth's marketing of diet drugs "to the extent Wyeth placed marketing or promotion ahead of health or safety concerns." Almost any proof related to negligence can be regarded as "related indirectly" to wanton conduct. Hypothetically, imagine that Clark calls a witness who will testify that Wyeth officials were made aware of VHD dangers and reached a decision that no warning should be published. PTO 2828 could be read to preclude this evidence because it is "indirectly related" to "wanton or similar conduct." Of course, the evidence is also highly probative of negligence.

Another hypothetical: Suppose Wyeth calls a witness who testifies that decisions about warnings are made only after careful evaluation of scientific evidence. Would PTO 2828 allow Clark's attorney to cross-examine on (still hypothetical) instances where marketing considerations were discussed in meetings about warnings?

Again, in the usual case counsel faced with such a question would ask the trial judge for guidance either by way of motion or sidebar. But PTO 2828 would make those questions fodder for the District Court, without a full appreciation of the flow of the testimony. Counsel might have to seek, for example, telephonic sidebars with the District Court. The order creates a highly intrusive and unworkable regulatory scheme.

Moreover, we emphasize, the rules imposed by PTO 2828 are not merely enforceable by the usual mechanism of the

trial court's sustaining objections or, perhaps, granting a mistrial. Here, a violation of the rule-a wrong guess-could result in a punitive sanction. There will be strong pressure on counsel to steer well clear of the line and possibly forego offering admissible evidence that Clark would normally expect to get before the jury.

This order is even more problematic insofar as it bans counsel from making argument "to the court" regarding these topics. Read literally (as counsel must), this would prevent Clark from even arguing to the state judge, outside the presence of the jury, that certain evidence falls within or outside the scope of PTO 2828. We do not think the District Court actually meant to preclude such argument. Indeed, it is hard to see what purpose would be served-and easy to see the problems that would arise-in restraining counsel from making arguments in state court. The point is that the District Court's understandable effort to lock the door against impermissible attempts to obtain exemplary damages led to an order that seriously interferes with Clark's rights to try her case.

Implicit in our discussion as well is the fact that PTO 2828 disrupts the state court's ability to manage its own judicial process. As the previous illustrations suggest, PTO 2828 would remove from the state judge a whole panoply of decisions that he or she would normally be authorized-indeed obliged-to make. But the process the order leaves is unclear. Some of the exclusions in the order are left to be applied by the state judge. Others are not. It is not clear, for example, whether the state judge would determine whether evidence is "related indirectly" to forbidden topics.

Appendix A

As we have held, the District Court had the unquestioned right to effectuate the restraints of the settlement through an order limiting opt-out plaintiffs' conduct in ancillary state proceedings. But we believe that that power must be exercised in a manner that minimizes entanglement in the state judge's ability to supervise judicial proceedings in his own courtroom. Similarly, the order should be fashioned in a manner that presumes that the state judge is capable and willing to enforce that settlement without close and intrusive supervision by the District Court.

III.

The settlement approved and supervised by the District Court in this case is a landmark effort to reconcile the rights of millions of individual plaintiffs with the efficiencies and fairness of a class-based settlement. Critical to this effort was the allowance of downstream opt-outs, so that potential class members were not faced with an all-or-nothing decision at the threshold. To make this allowance meaningful, the settlement had to protect Wyeth against its largest fear, potentially ruinous punitive damage awards. At the same time, it had to allow intermediate opt-out plaintiffs to have a fair chance to litigate their claims and obtain those damages that were expressly preserved.

The District Court had, and still has, the power to effectuate and protect the terms of this bargain. But in doing so, the Court must be mindful of two limiting considerations: (1) opt-outs must be able to fairly litigate the claims preserved to them under the agreement, and (2) intrusion into state court proceedings should be minimized.

Accordingly, the District Court erred in imposing the evidentiary restrictions of PTO 2828 because those restrictions were overbroad and impinged on plaintiffs' rights under the settlement, and they unduly entangled the Court in the management of separate state court proceedings. PTO 2828's pre-trial evidentiary restrictions survive these limiting principles only insofar as they prohibit opt-outs from offering evidence that is relevant *exclusively* to forbidden damages. *See* PTO 2828, ¶¶ (3)(a)-(b). As appellants themselves concede, an injunction to that effect is entirely permissible.

Specifically, the following portions of PTO 2828 must be vacated: (i) the categorical evidentiary restrictions in Subsections (2)(b)-(c) and Subsections (3)(c)-(h), insofar as they preclude plaintiffs from introducing evidence relevant to proving their VHD claims in state court; and (ii) the limitations on exhibits and deposition testimony in Section (4), insofar as they preclude plaintiffs from introducing evidence relevant to proving their claims in state court. PTO 2828 is consistent with this opinion insofar as it prohibits plaintiffs from "introducing any evidence" relevant exclusively to "punitive, exemplary or multiple damages, however described," which specifically includes evidence of "(a) Wyeth's profits, size or financial condition"; and "(b) the amount or size of Wyeth's sales of diet drugs or other products."

PTO 2828 also runs afoul of this opinion insofar as it prohibits the parties from "making any statement or argument to the court." But the order is consistent with this opinion insofar as it prohibits the parties from "making any statement

or argument to the . . . jury related directly" to evidence relevant only to punitive damages.[13]

We note that although we have limited the District Court's ability to prohibit the parties from offering certain evidence in their state court trials, the state courts are presumably mindful of the obligation to honor the settlement agreement, and to ensure that the parties do not evade it. That will undoubtedly impel the state courts during trial to exclude evidence when its prejudicial effect (namely its tendency to inflame the jury and improperly inflate compensatory damages) outweighs its probative value. We are confident, particularly in light of the previous state court orders in the record, that the state courts can and will capably manage this task.

In addition, our opinion leaves the District Court free to consider other measures, aside from imposing evidentiary restraints, that will effectuate the limitations of the settlement agreement. The District Court might consider, for example, ordering language to be included in a stipulation or proposed jury instruction that would make it clear to the jury that exemplary damages may not be awarded. Or, the Court could direct the parties to agree to a bifurcated trial-where damages are determined apart from liability-in the event that the state court were to deem it advisable.

---

13. Although we specifically address PTO 2828, the most comprehensive order, we expect that the District Court will modify all orders at issue in this appeal so that they are consistent with this opinion.

Moreover, while we understand the desirability of taking steps to protect the settlement agreement before a trial occurs, the District Court is not without recourse in the event that a verdict is rendered that appears to grant punitive damages under the guise of some other damage category. The precise circumstances that might arise are too speculative to discuss with specificity. But post-trial remedies should not be categorically rejected.[14]

We recognize that the District Court's task is a difficult one, particularly in light of the patent efforts by plaintiffs' counsel to press against the damages restrictions to which intermediate opt-outs are bound. But the Court's power has to be exercised consistent with the terms of the notice and agreement on which potential class members relied at the outset of the process. Moreover, it has to be applied to the state courts with appropriate consideration for limitations of equity, federalism, and comity.

---

14. At oral argument, we raised the question whether the District Court had power after a verdict to limit or remit a damage award that seemed so excessive that it amounted to exemplary damages. We particularly focused on the *Rooker-Feldman* doctrine. This decision is not the proper place to consider fully the extent to which the *Rooker-Feldman* doctrine might circumscribe the District Court's ability to effectuate the agreement's punitive damages provision after a jury has awarded a plaintiff damages. We note, however, that where "a federal court's proper exercise of its jurisdiction to manage its cases has the secondary effect of voiding a state court determination, it is not a review of that order for purposes of the *Rooker-Feldman* doctrine." *Diet Drugs I*, 282 F.3d at 242. On the other hand, the Full Faith and Credit Act, 28 U.S.C. § 1738, precludes a federal court from reconsidering a state court's judgment as to the preclusive effect of a federal court judgment. *See Parsons Steel, Inc. v. First Ala. Bank*, 474 U.S. 518 (1986).

Accordingly, we will vacate the Court's injunctions and remand with instructions to modify them in accordance with this opinion.

APPENDIX B — MEMORANDUM AND PRETRIAL ORDER NO. 3088 OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA DATED OCTOBER 30, 2003

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT
OF PENNSYLVANIA

MDL NO. 1203

CIVIL ACTION NO. 99-20593

IN RE: DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS CORPORATION

MEMORANDUM AND PRETRIAL ORDER NO. 3088

Bartle, J.

Wyeth has filed a motion to enjoin plaintiff class members and their counsel in the cases of *Eichmiller v. American Home Products Corp.*, Civil Action No.2002CV52077 (Fulton County, Georgia), *Cook, et al. v.*

Appendix B

Wyeth, Cause No.2002-21 (Hinds County, Mississippi), and *Caldwell v. American Home Products Corp.*, No.2002-113-CV3 (Jones County, Mississippi) from introducing evidence at trial related to the "four cases label" for the diet drug Pondimin and to the "black box warning" for the diet drug Redux for the years 1995 and 1996. Wyeth contends the introduction of such proof would violate the Nationwide Class Action Settlement Agreement ("Settlement Agreement") in this multidistrict litigation.

Under the Settlement Agreement, approved in Pretrial Order ("PTO") 1415, class members who are suffering from left-sided valvular heart disease ("VHD") may exercise either an immediate or back-end opt-out under certain conditions. By exercising such a downstream opt-out, as plaintiffs have done here, they may sue Wyeth in the tort system for compensatory damages. However, the Settlement Agreement forbids them from suing Wyeth for punitive, exemplary, or multiple damages. See Settlement Agreement §§ IV.D.3.C. and IV.D .4.C.

Underlying Wyeth's motion is its effort to prevent any mention of primary pulmonary hypertension ("PPH"), a progressive disease which is virtually always fatal. In a number of previous pretrial orders, we have enjoined plaintiffs and their counsel in other lawsuits from introducing such evidence because it was clearly designed to inflame the jury to award punitive damages. See PTO 2680. The plaintiffs here allege that they are suffering from VHD and not from PPH. Consequently, any effort to inject PPH into their trials can only be for the purpose of obtaining punitive damages, in fact if not in name. *See* PTO 2828. Because the offer of

such evidence would clearly be in breach of the Settlement Agreement, we have authority to prevent plaintiffs from doing so. *See In re Prudential Insur. Co. of Am. Sales Practice Litig.*, 261 F.2d 355 (3d Cir.2001). Any procedural, evidentiary, or substantial rule of law of any state must yield to the terms of the Settlement Agreement and specifically its punitive damages exclusion. *See* PTO 2818; PTO 2680.

The "four cases label" for the diet drug Pondimin stated:

> There have been four causes [sic] of pulmonary hypertension reported in association with fenfluramine use. Two cases were apparently reversible after discontinuation of fenfluramine, but evidence of pulmonary hypertension recurred in one of these patients upon rechallenge with fenfluramine. A third patient was initially improved with nifedipine treatment, but was noted to have increased pulmonary arterial pressure again at a four month follow up visit. Finally, an irreversible and fatal case of pulmonary hypertension has been reported in a patient who had seven 1-month courses of fenfluramine in the twelve years prior to death. Patients taking fenfluramine should be advised to report immediately any deterioration in exercise tolerance.

Pulmonary hypertension ("PH") is a quite common phenomenon in the general population and should not be confused with the fatal disease known as PPH. PH, which involves an elevation in pulmonary artery pressure, is a

symptom caused by various conditions, including high blood pressure. PH can also be secondary to VHD.

While the four cases label uses the term PH rather than the term PPH, a review of the record as well as the wording of the four cases label itself demonstrates that it is describing PPH. The four cases referred to in the label were actually cases of PPH. The plaintiff in Caldwell, supra, concedes as much in her answer to an interrogatory. Clearly the references to PH are not to PH secondary to VHD.

The "black box warning" concerns the warning label the Food and Drug Administration ("FDA") was considering in 1995 and 1996 in connection with the approval of the diet drug Redux and whether the warning should be enclosed within a black border, that is, a black box. There can be no doubt, and plaintiffs do not really challenge, that the discussions with the FDA during this time period centered on a warning for PPH and not PH secondary to VHD.

At the time we entered PTO 2828, we did not have enough information to decide the issue now before the court. Thus, we deferred to the trial judge to determine whether evidence involving the four cases label and the black box warning related to PH or to PPH. Now, having a more complete record, we are convinced that issues of "the four cases label" and "the black box warning" concern PPH, and not PH or even PH secondary to VHD.[1]

---

1. If a plaintiff were allowed to introduce evidence, however spurious, that the four cases label is about PH secondary to VHD and not about PPH, Wyeth would face the necessity of introducing

(Cont'd)

Appendix B

We made it quite clear in PTO 2828, as well as other PTO's, and we reiterate here that class members and their counsel may not make any reference, directly or indirectly, to PPH at any trial where class members are suing Wyeth for VHD. Likewise, they may not mention PH, except as a secondary condition to VHD. We now rule that these prohibitions specifically prevent reference to evidence related to the "four cases label" for Pondimin and evidence related to the "black box warning" in 1995 and 1996 for Redux. The offer and introduction of such proof would violate the provisions of the Settlement Agreement against claims for punitive, exemplary, or multiple damages.

We will grant Wyeth's motion and enter the attached injunction.

(Cont'd)
truthful evidence that it really is about PPH. A plaintiff would thus have achieved indirectly what the Settlement Agreement forbids, that is, the introduction of the inflammatory issue of PPH into a case involving VHD.

Appendix B

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT
OF PENNSYLVANIA**

MDL NO. 1203

CIVIL ACTION NO. 99-20593

IN RE: DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS CORPORATION

PRETRIAL ORDER NO. 3088

AND NOW, this 30th day of October, 2003, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the plaintiffs and their agents, attorneys, and derivative claimants are ENJOINED in the cases of *Eichmiller v. American Home Products Corp.*, Civil Action No.2002CV52077 (Fulton County, Georgia), *Cook, et al. v. Wyeth*, Cause No.2002-21 (Hinds County, Mississippi), and

Appendix B

Caldwell v. American Home Products Corp., No.2002-113-CV3 (Jones County, Mississippi) from introducing any evidence, making any statement before or argument to the court or jury, related directly or indirectly to:

(a) punitive, exemplary or multiple damages, however described;

(b) malicious, wanton or other similar conduct of Wyeth, however described;

(c) any medical condition of plaintiffs caused by Wyeth other than left-sided mitral valve regurgitation or pulmonary hypertension secondary to mitral valve regurgitation;

(d) Wyeth's profits, size or financial condition;

(e) the amount or size of Wyeth's sales of diet drugs or other products;

(f) Wyeth's marketing or promotion of diet drugs to the extent that Wyeth placed marketing or promotion ahead of health or safety concerns;

(g) any deception or any destruction, hiding, overwriting, or deliberate miscoding of documents or information by Wyeth;

(h) any involvement by Wyeth in the ghostwriting of articles;

Appendix B

(i) primary pulmonary hypertension;

(j) neurotoxicity;

(k) any other disease, illness or condition or persons suffering from any other disease, illness or condition caused by Redux or Pondimin except for left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease; and

(l) the "four cases label" for Pondimin and the "black box warning" for Redux in 1995 and 1996; and

(2) the parties shall deliver forthwith to the state trial judges a copy of this Memorandum and Pretrial Order.

BY THE COURT:

s/ Harvey Bartle
Harvey Bartle, J.

APPENDIX C — PRETRIAL ORDER NO. 2883 OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA DATED JUNE 10, 2003

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MDL No. 1203

Civil Action No. 99-20593

IN RE DIET DRUGS (PHENTERMINE/ FENFLURAMINE/ DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION

This document relates to:

SHEILA BROWN, *et al.*

v.

AMERICAN HOME PRODUCTS CORPORATION

Pretrial Order No. 2883

The Court, having considered Wyeth's Motion For Injunctions To Enforce The Nationwide Class Action Settlement Agreement ("Motion to Enforce") in the actions entitled *Wilson, et al. v. Wyeth, et al.*, No. 3:03cv305BN (S.D. Miss.) and *James, et al. v. Wyeth et al.*, No. 2002-95 (Smith County, Miss.) (the "Mississippi Actions"), and the submissions of counsel presented in support of and

opposition to the Motion to Enforce, and finding good and just cause therefor,

IT IS HEREBY ORDERED that Wyeth's Motion to Enforce is GRANTED; and

IT IS FURTHER ORDERED that:

(1) Plaintiffs Keith K. Barlow, Ruby S. Barlow, Cherry Barnes, Joe Wayne Burton, Nora K. Burton and Lonelle S. James, in the case of *James, et al. v. Wyeth, et al.*, No. 2002-95, pending in the Circuit Court of Smith County, Mississippi (the "James Plaintiffs"), and the respective agents, attorneys and derivative claimants, are, each of them, ENJOINED from introducing any evidence, making any statement before or argument to the court or jury, related directly or indirectly to:

(a) punitive, exemplary or multiple damages, however described;

(b) malicious, wanton or other similar conduct of Wyeth, however described; and

(c) any medical condition of plaintiff caused by Wyeth other than left-sided valve regurgitation or, for those plaintiffs who allege it, pulmonary hypertension secondary to mitral valve regurgitation;

and

(2) Without limitation as to the scope of the injunction set forth in paragraph 1, the *James* Plaintiffs, and their respective agents, attorneys and derivative claimants, are, each of them, ENJOINED from introducing any evidence or making any statement before or argument to the court or jury related directly or indirectly to the following subjects:

(a) Wyeth's profits, size or financial condition;

(b) the amount or size of Wyeth's sales of diet drugs or other products;

(c) Wyeth's marketing or promotion of diet drugs to the extent that Wyeth placed marketing or promotion ahead of health or safety concerns;

(d) any deception or any destruction, hiding, overwriting, or deliberate miscoding of documents or information by Wyeth;

(e) any involvement by Wyeth in the ghostwriting of articles;

(f) primary pulmonary hypertension;

(g) neurotoxicity; and

(h) any other disease, illness or condition or persons suffering from any other disease, illness or condition caused by Redux or Pondimin except for left-sided valvular heart

disease or, for those plaintiffs who allege it, pulmonary hypertension secondary to mitral valvular heart disease;

and

(3) Without limitation on the scope of the injunctions set forth in paragraphs 1 and 2, the *James* Plaintiffs, and their respective agents, attorneys and derivative claimants, are, each of them, ENJOINED from introducing (a) any exhibit or deposition testimony which was not included in (i) the Third Amended Exhibit List (as such exhibits were redacted) or which was withdrawn by plaintiff from such list, as reflected in Pretrial Order No. 2828 and its accompanying Memorandum and Pretrial Order No. 2865, or (ii) the Sixth Amended Deposition Designations submitted to this Court on March 21, 2003 by Plaintiff Clara Clark pursuant to Pretrial Order No. 2717 (together, the "Proffered Clark Trial Plan"),[1] and (b) any exhibit (or portion of an exhibit) or deposition testimony (or portion of deposition testimony) included in the Proffered Clark Trial Plan, or making any statement before or argument to the court or jury in the James action related directly or indirectly to those exhibits and that deposition testimony or the contents thereof,

---

1. A copy of the Clark Third Amended Exhibit List, the exhibits (with the Clark plaintiff s redactions), the Clark Sixth Amended Deposition Designations and the text of the Clark plaintiff's designated testimony are attached hereto as Exhibits "A," "B," "C" and "D," respectively, and are incorporated into this Order.

except as allowed in Pretrial Order No. 2828 and its accompanying Memorandum and Pretrial Order No. 2865[2]; and

(4) The parties shall deliver forthwith to the presiding court in the James action a copy of this Order, including the exhibits attached hereto.

SO ORDERED THIS 10th DAY OF JUNE 2003

s/ Harvey Bartle
HARVEY BARTLE, III, J.

---

2. A copy of Pretrial Order No. 2828 and its accompanying Memorandum and Pretrial Order No. 2865 are attached hereto as Exhibits "E" and "F", respectively, and are incorporated into this Order.

APPENDIX D — MEMORANDUM AND PRETRIAL ORDER NO. 2828 OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA DATED APRIL 8, 2003

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MDL Docket No. 1203

CIVIL ACTION NO. 99-20593

IN RE: DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO

SHEILA BROWN, et al.,

v.

AMERICAN HOME PRODUCTS CORPORATION.

MEMORANDUM AND PRETRIAL ORDER NO.2828

Bartle, J. April 8, 2003

This Memorandum and Pretrial Order is an outgrowth of injunctions we entered against class member Clara Clark and her counsel because of their attempt to inject into the case of *Clark v. Wyeth, et al.*, No. B020182-C, pending in the District Court of Orange County, Texas, the issue of

punitive damages in violation of the Nationwide Class Action Settlement Agreement involving the diet drugs commonly known as "fen-phen." See Memorandum and Pretrial Order ("PTO") 2625 (Oct. 16, 2002) and Memorandum and PTO 2717 (Jan. 29, 2003).

I.

The Nationwide class Action Settlement Agreement, which was approved by the court in PTO 1415, allows class members under certain circumstances to opt out of the settlement and sue Wyeth for damages in the tort system. Ms. Clark, as was her right, exercised what is known as an intermediate opt-out and brought an action against Wyeth in the state court in Texas. She had ingested Redux, one of the fen-phen drugs. Despite her opt-out, Ms. Clark still remains a class member and is bound by the terms of the Settlement Agreement even though she has elected her opt-out right. See Settlement Agreement §§ II.B. and IV.D.3. Under the Settlement Agreement, persons electing to sue Wyeth rather than to receive what are known as Matrix benefits are prohibited from seeking "punitive, exemplary, or multiple damages" against settled parties, including Wyeth. settlement Agreement § IV.D.3.c; see Memorandum and PTO 2625.

The current controversy had its genesis in a motion filed by Wyeth in this multi-district litigation ("MDL") court to enjoin plaintiff class member and her counsel from seeking such damages in her state court lawsuit. For the reasons stated in PTO 2625, this court found that they were seeking to insert the issue of punitive damages (in fact although not in name) into the case as evidenced by papers they had filed with the

state court as well as by some of the exhibits and testimony they intended to introduce at the trial. Consequently, we enjoined plaintiff and her counsel from doing so.[1] Unfortunately, while they withdrew a few objectionable exhibits, their subsequent filings with the state court clearly demonstrated that they did not intend to comply with this court's injunction. Even the Texas trial judge concluded that Ms. Clark and her counsel were continuing to press for punitive damages. PTO 2717 at 4. Wyeth thereafter filed a motion for civil contempt against Ms. Clark's counsel, George M. Fleming, Esquire of Houston, Texas. After a hearing, the court found Mr. Fleming in civil contempt and further enjoined plaintiff and her counsel from trying the case in the Texas state court until counsel purged himself and satisfied the court they would not seek punitive damages in violation of the Nationwide Class Action Settlement Agreement. See PTO 2717 ¶ 2; *In re Prudential Ins. Co. of Am. Sales Practices Litig.*, 261 F.3d 355, 364 (3d Cir. 2001). The prohibition against punitive damages is a critical provision for which Wyeth bargained and which received court approval after a lengthy fairness hearing in May, 2002. *See* Memorandum and Pretrial Order No. 1415 (Aug. 28, 2000).

---

1. The court also had entered a similar injunction against the plaintiff and her counsel, the same George Fleming, in the case of *Smart v. American Home Products Corp.*, No. 02-04-40259-CV, pending in the District Court of Jim Wells County, Texas. See PTO 2680 (Dec. 11, 2002).

This issue has serious ramifications far beyond the Clark case. As we explained in PTO 2717:

> If George Fleming is allowed to proceed as he wishes here, others will not be far behind. The floodgates will open and the prohibition against punitive damages in the court approved Settlement Agreement will be nothing but a dead letter, with potentially dire consequences for the settlement as a whole. This court has a special responsibility to prevent this outcome from happening.

Our Court of Appeals has repeatedly recognized the power of the federal court overseeing a nationwide class action settlement to issue an injunction under the "in aid of its jurisdiction" exception to the Anti-injunction Act, 28 U.S.C. § 2283, Most recently, in upholding the District court's issuance of such an injunction, our Court of Appeals cogently stated:

> We have recognized that district courts overseeing complex federal litigation are especially susceptible to disruption by related actions in state fora. *In re Diet Drugs*, 282 F.3d at 235-36. Undeniably, this one discrete case would have provided little disruption to an eight-million-member class action. But while the Illinois litigation would not have brought down the settlement on its own, permitting this kind of action would open up the possibility of a large, or even an overwhelming, number of collateral

attacks on the settlement itself, especially given the eight-million-member class.

In re Prudential Ins. Co. of Am. Sales Practices Litig., 314 F.3d 99, 104 (3d Cir. 2002).

Our goal is and has always been to allow Ms. Clark to have her day in the Texas court as soon as possible as long as it is in conformity with the Settlement Agreement. As a result, we urged the parties to meet after the injunctions were entered to see if they could resolve the dispute over specific exhibits and testimony which plaintiff intended to introduce at the trial and which Wyeth contended were designed to arouse the jury to award punitive damages. Until these issues were resolved, Ms. Clark's case would not go to trial. A meeting of counsel took place but was not fruitful.

It has now become clear to the court that the only effective way to safeguard the Settlement Agreement is to enter a detailed order before trial outlawing specific topics of inquiry which have the sole or predominant purpose of inflaming the jury to punish Wyeth and excluding individual exhibits and deposition testimony going to the issue of punitive damages. As a practical matter, once the trial is underway it will be too late for this court to prevent any breach of the Settlement Agreement.

II.

The court held a lengthy status conference with counsel on March 25, 2003 to review and rule on over a hundred exhibits to determine whether they run afoul of the Settlement

Agreement's prohibition and this court's injunctions. We also have read numerous pages of contested deposition testimony. The purpose of our review is narrow. We recognize that our role is not to try the Clark case or to dictate plaintiff's trial strategy, but simply to prevent a class member from breaching the prohibitions in the Settlement Agreement against punitive damages. As previously noted in PTO 2717, a party may not rely on state evidentiary rules, or procedural or substantive law to override the punitive damage exclusion of the Settlement Agreement.

In reviewing the history of the case as well as the particular exhibits and deposition testimony in question, a number of subjects stand out which relate solely to the issue of punitive damages or whose probative value is clearly outweighed by the unfair prejudice to Wyeth with respect to punitive damages. Consequently, in order to uphold the Settlement Agreement pursuant to PTO 1415 and to eliminate as much chance for evasion as possible, we will enjoin plaintiff and her counsel from introducing evidence or making any statement before or argument to the court or jury related directly or indirectly to these subjects. They are: (a) Wyeth's profits, size or financial condition; (b) the amount or size of Wyeth's sales of diet drugs or other products; (c) Wyeth's marketing or promotion of diet drugs to the extent that Wyeth placed marketing or promotion ahead of health or safety concerns; (d) any deception or any destruction, hiding, overwriting, or deliberate miscoding of documents or information by Wyeth; (e) any involvement by Wyeth in the ghostwriting of articles; (f) primary pulmonary hypertension; (g) neurotoxicity; and (h) any other disease, illness or condition or persons suffering from any other disease, illness

or condition caused by Redux or Pondimin except for left-sided mitral valve regurgitation or pulmonary hypertension secondary to left-sided mitral valve regurgitation.

Subjects (a) through (c) have no relevance whatsoever to whether Redux caused Ms. Clark's current medical condition. They focus on Wyeth's wealth, size, or overriding financial motives which have nothing to do with the merits of the case and everything to do with punishment of Wyeth. Subjects (d) and (e), concerning any deception or any destruction, hiding or deliberate miscoding of documents or information or the ghostwriting of articles paid for by Wyeth are designed to demonstrate willful, wanton or malicious conduct rather than negligence or strict liability. Subject (f) dealing with primary pulmonary hypertension ("PPH") and subject (g) dealing with neurotoxicity can have no other purpose in this case than to inflame the jury to award more than compensatory damages. PPH is a fatal, although rare, condition allegedly caused by fen-phen. Gratefully, Ms. Clark does not claim to suffer from such a condition. Likewise, she has not been diagnosed with neurotoxicity, a serious brain injury allegedly resulting from exposure to fen-phen. Plaintiff's effort to inject subject (h) can have no legitimate purpose to prove her claim for compensatory damages. She alleges only that she has left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. Other illnesses or persons suffering from other illnesses caused by Redux or fen-phen can only have the effect of unfairly arousing the jury against Wyeth without otherwise supporting her allowable claims under the Settlement Agreement.

Appendix D

There have been numerous disputes between the parties over whether Wyeth's use of the term pulmonary hypertension ("PH") in various exhibits meant PPH or simply pulmonary hypertension. There is a significant difference between the two. As noted above, PPH is a fatal condition. As a result, we have forbidden any mention of PPH since Ms. Clark did not suffer from it, and plaintiff has previously agreed to redact all references to PPH and any discussion about it. What Wyeth meant in any particular instance when it used the term pulmonary hypertension will have to be decided by the trial judge based on the facts before him. If plaintiff's reference to Wyeth's use of PH does not include any reference to PPH or the tragic consequences of PPH and is limited to pulmonary hypertension secondary to left-sided valvular heart disease, we will not disallow the reference since it does not implicate punitive damages. Accordingly, where the phrase "pulmonary hypertension" or PH is used, we will defer to the trial judge who will be in a better position to make a ruling on proffered exhibits and testimony consistent with this court's PTO.

We recognize that the Settlement Agreement permits a class member to bring a claim related to marketing and promotion of Pondimin and Redux. However, plaintiff may not inject the issue of marketing and promotion to circumvent the prohibition on subjects (a) and (b). Nor may plaintiff attempt to prove or argue that Wyeth put marketing or promotion of these drugs ahead of the consumer's health or safety. These off-limits areas of inquiry are not necessary to prove Ms. Clark's compensatory claims and can have no other purpose than to obtain punitive damages.

Appendix D

At the status conference, there was also disagreement over exhibits related to the use and contents of a "black box" on the drug warning label. We will not prohibit evidence on this subject so long as it does not reference PPH or its tragic consequences. What the label did or did not contain goes to the issue of failure to warn and does not implicate punitive damages if plaintiff does not endeavor to prove or argue any deception of the Federal Drug Administration ("FDA") or anyone else. Plaintiff may certainly attempt to prove that relevant warnings were inadequate or wrong and that certain relevant information was not reported or not reported on a timely basis to the FDA. Plaintiff, however, may not prove or argue that any such failure was deliberate or intentional or an act of deception because such conduct connotes more than negligence and is unnecessary to establish strict liability. Again, the only purpose for injecting flagrant conduct into the trial is to attempt to punish Wyeth.

III.

Prior to the March 25, 2003 status conference, counsel for Ms. Clark agreed to withdraw or redact certain exhibits. In omitting any further comment, we are relying on the agreement of the parties that these exhibits or parts of exhibits will not surface at the trial. In addition, during the March 25 conference, Wyeth withdrew its objections to Exhibits P-17, P-18, P-25, P-29, P-150, P-229, P-273, P-341, P-342, P-465, P-692, P-819, P-820, and P-823, and Ms. Clark's counsel withdrew Exhibits P-90, P-647, P-687, P-695, P-763, P-802, P-859, and P-861 - No further ruling as to them is necessary.

Appendix D

In light of the above discussion, we make the following rulings on Wyeth's objections to plaintiff's remaining trial exhibits and designations of deposition testimony, some of which, we reiterate, contain previously agreed upon redactions not referenced here.

A. Exhibits re: Conditions other than Left-Sided Valvular Heart Disease or Pulmonary Hypertension Secondary to Left-Sided Valvular Heart Disease.

1. Exhibit P-2: Summary of Adverse Drug Events (Denoted by VIGI or MCN Number);

2. Exhibit P-22: August 23, 1995 Clinical Drug Safety Surveillance Report-Pondimin;

3. Exhibit p-62: June 5, 1996 clinical Drug Safety Surveillance on Cardiovascular System;

4. Exhibit P-81: November 1995 Confidential Post Marketing Surveillance — Redux;

5. Exhibit P-88: August 17, 1995 memo from Moeller to Olsen re: Pondimin ADE Tabulation Reports;

6. Exhibit P-89: August 17, 1995 Clinical Drug Safety Surveillance Report;

7. Exhibit P-117: December 19, 1994 Confidential Postmarketing Safety Update for Dexfenfluramine;

8. Exhibit p-262: August 29, 1997 Dossier from Servier to Deitch re: Cardiac Adverse Effects of Fenfluramine Isomers;

9. Exhibit P-402: September 6, 1996 memo from Moeller to CV/NSAID/Met Therapeutic Group re: Modification of Dictionaries; and

10. Exhibit P-463: April 15, 1996 Medical Officer's Review of Dexfenfluramine;

11. Exhibit P-839: Clinical Data Safety Surveillance System/List of all Drug Experience Reports for Fenfluramine.

Wyeth objects to the above exhibits on the grounds that each contains references to Adverse Drug Events ("ADE") or medical conditions associated with the diet drugs that do not relate to left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease, the conditions from which Ms. Clark allegedly suffers. Wyeth contends that any reference to such adverse events or conditions is intended to go beyond the seeking of compensatory damages. We agree, and the objection will be sustained to the extent that the plaintiff shall redact any and all references to adverse events or medical conditions that do not relate to left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. We note that counsel for Ms. Clark did not object to the limitation on Exhibit P-262; however, counsel has requested that her experts be allowed to rely on the entire exhibit to form certain opinions relevant to the legal issues in the case. We will defer to the trial court judge on this matter.

Appendix D

In addition, plaintiff shall redact the following language from Exhibit P-463:

(a) paragraphs 1.a, 1.b, 1.c and 1.d on bates stamped page AHP-Q- 00075285;

(b) paragraphs 2 and 3 on bates stamped page AHP-Q-00075286,

(c) the sentence beginning with "Furthermore, this warning must appear" that begins on the bottom of bates stamped page AHP-Q-00075286 and ends on the top of bates stamped page AHP-Q-00075287; and

(d) paragraph 6 on bates stamped page AHP-Q-00075287

12. Exhibit P-S2: October 26, 1995 memo from Lauger to Deitch re: Contact Report Meeting.

Wyeth objects to the use of Exhibit P-82 on the basis that it refers amorphously to the dangers associated with Redux, and therefore is relevant only to the issue of punitive damages. We will sustain the objection. Among other things, the exhibit states, "[w]hen asked about the public awareness of [Redux], he stated that it is quite high, but the public is increasingly concerned and afraid of the drug" (emphasis added). In light of this, we believe that the exhibit has no relevance other than to obtain a punitive award.

Appendix D

B. Exhibits re: Ghostwriting.

13. Exhibit P-45: 1996 and 1997 Dexfenfluramine Publication Plans and 1997 Weekly Status Reports,

14. Exhibit P-415: August 19, 1996 fax from Coble-D'Angelo to Dolan re: Comments from Dr. Atkinson on Dexfen review paper, etc.;

15. Exhibit P-478: March 4, 1996 memo from Dolan to Distribution re: Manuscript, and

16. Exhibit P-801: "Whose article is it anyway?" Article from the Lancet, July 10, 1999.

Wyeth objects to Exhibits P-45, P-415, P-478 and P-801 on the ground that each relates in some degree to Wyeth's involvement in the practice of paying ghostwriters to author studies concerning its diet drugs. Evidence and argument concerning ghostwriting, it contends, only serve to inflame the jury to punish Wyeth for its alleged dishonest conduct. Plaintiff, however, has asserted that evidence as to ghostwriters is relevant in part to help assess the reliability of the articles. We will sustain the objections.

Accordingly, Exhibits P-45 and P-801 shall be stricken in their entirety. Exhibit P-415 shall be redacted by blacking out on bates stamped page AHP-EM-00011432: (1) the entire paragraph beginning with "Let me congratulate you" and (2) the phrase "this piece may make dexfenfluramine sound

better than it really is" in the final paragraph. Exhibit P-478 shall be redacted by blacking out on bates stamped page AHP-Q-00037451 the sentence beginning with "Attached please find a review article . . . ."

We emphasize that we will not prohibit plaintiff from calling attention to the fact that Wyeth may have funded certain articles. This, we believe, goes directly to the reliability or credibility of the articles. Plaintiff may also challenge the accuracy of any article. Plaintiff will not, however, be permitted to argue that the person whose name appears on the article is not the person who actually authored it.

C. Exhibits re: Neurotoxicity.

17. Exhibit P-19: September 10, 1997 E-mail from Acri to Barton with attachment,

18. Exhibit P-119: October 28, 1994 memo from Hasking, Baranello to Derivan and Victoria re: Dexfenfluramine meeting with Assessment,

19. Exhibit P-164.15: Dr. Gerald Polukoff's Reports/cardiology evaluation of Clara Clark,

20. Exhibit P-463: April 15, 1996 Medical Officer's Review of Dexfenfluramine, and

21. Exhibit P-834: Questions and Answers about Redux

Appendix D

Wyeth objects that Exhibits P-19, P119, P-164.15, P-463 and P-834 are punitive in nature because each references the issue of neurotoxicity. Any reference to neurotoxicity is irrelevant and will only be used to the unfair prejudice of Wyeth by demonstrating that fen-phen causes neurotoxicity, a serious condition that Ms. Clark does not have. The objections will be sustained. Therefore, Exhibit P-19 shall be redacted to remove on bates stamped page AHP-W-00190027 "Neurochemical Findings in Animals" and, in addition, the first five paragraphs on bates stamped page AHP-W-00180028.[2] Exhibit 164.15 shall be redacted by blacking out on bates stamped page SRS0022 the following language in the last paragraph: "fenfluramine toxicity, affecting the pulmonary vasculature directly and by" Plaintiff shall remove from Exhibit P-463 Paragraph 1 under the heading "Medical Officer's Comment and Recommendations" on bates stamped page AHP-Q-00075286. All references in Exhibit P-834 to neurotoxicity also shall be stricken. Finally, Exhibit P-119 shall be redacted as follows:

(a) the second bullet point under the "Summary" heading on bates stamped page AHP-Q-00180996;

(b) the paragraph beginning with "Dr. Sandage" on bates stamped page AHP-Q-00180997 and ending with "planned to confirm this analysis" on bates stamped page AHP-Q-00180998; and

---

2. Ms. Clark's counsel did not object to these deletions.

(c) the paragraph beginning with "Dr. Moore (Consultant) and others" on bates stamped page AHP-Q-00180998.

Plaintiff shall redact as well any reference to neurotoxicity in Exhibits P-94 and P-493. Exhibit P-493 specifically shall be redacted to black out paragraph 3 on bates stamped page AHP-Q-00138942.

D. Exhibits re: PPH and the Distinction Between PH/PPH.

22. Exhibit P-l: Time line of Pondimin and Redux Labeling Issues;

23. Exhibit P-20: August 28, 1997 letter from Joseph Sonk to Dr. Solomon Sobel;

24. Exhibit P-59 and P-60; July 9, 1996 memo from Myers/Levine to Distribution;

25. Exhibit P-95: Pulmonary Hypertension and Pondimin Statement;

26. Exhibit P-101: May 31, 1995 DCSSS printout re: Pondimin PPH;

27. Exhibit P-141: August 9, 1991 letter from Lyers to Maillere (Servier) with copy of Wyeth's summary of increased incidence of PPH with fenfluramine use in Belgium; and

Appendix D

28. Exhibits P-159.01 to P-159.14, P-160.01 to P-160.04, and P-203 (Physicians' Desk References re: Pondimin or Redux).

Wyeth objects to these exhibits on the basis that they refer to cases of PPH. Although the exhibits may not reference PPH specifically, each discusses PH of which PPH is a subset. We will overrule the objections. As we have noted above, the trial court will be in a better position to rule on whether a specific reference to pulmonary hypertension or PH also means PPH. However, as long as plaintiff's reference to the exhibit or Wyeth's use of PH in that exhibit does not include any reference to PPH or its devastating consequences and is limited to pulmonary hypertension secondary to left-sided valvular heart disease, we will not prohibit the reference as suggestive of punitive damages. We will overrule the objection to Exhibit P-203, which is a duplicate of Exhibit p-160.03.

29. Exhibit P-4: Dr. Fishman article, "Aminorex to Fen-Phen,"

30. Exhibit P-61: July 3, 1996 memo from Acri to List re: Pondimin Labeling; and

31. Exhibit P-102: May 26, 1995 Acri memo to Sickles re: Pondimin Proposed Labeling Revisions.

Wyeth objects to these exhibits as follows. First, it contends that Exhibit P-4 makes reference to theories as to how fen-phen can damage the pulmonary vasculature, which

plaintiff may use to discuss PPH. Second, Wyeth anticipates that plaintiff will use Exhibit P-61 in connection with arguments about the accuracy of the Pondimin label on PPH from 1987 through 1996, Third, it objects that certain language in Exhibit P-102 makes an improper reference to PPH. Specifically, it asserts that the redacted material on bates stamped page AHP-P-00010257, together with the language "[d]iscontinuation of fenfluramine with subsequent treatment usually resulted in either abatement of the condition or clinical and hemodynamic stabilization or improvement," refers to circumstances that occur when an individual is diagnosed with PPH.

As we have determined above, the trial court will be in a better position to make a ruling on these proffered exhibits. However, we reiterate that as long as plaintiff's use of the exhibit does not include any reference to PPH or its devastating consequences and is limited to pulmonary hypertension secondary to left-sided valvular heart disease, we will not prohibit the use as suggestive of punitive damages. The objections otherwise are overruled.

Wyeth's objection to the subtitle "An Epidemic Foretold," in Exhibit P-4 is sustained. The language is punitive in nature and shall be redacted.

32. Exhibit P-65: February 27, 1996 E-Mail from Dolan to Swat Team re: Redux Label; and

    Exhibit P-78: November 22, 1995 memo from Bathish to Hassan re: Dexfenfluramine Assessment.

Appendix D

Wyeth objects to Exhibits P-65 and P-78 on the ground that together they reference cases of PPH and Wyeth's desire to avoid a "black-box" warning on PPH. The objection to Exhibit P-65 will be overruled. The punitive nature of the exhibit is not apparent on the face of the document. The objection to Exhibit P-78 will be sustained only to the extent that it shall be redacted to eliminate the following language in the first full paragraph on bates stamped page AHP-Q-00013941: "every attempt will be made to ensure that no 'Black Box' Warnings, restrictions of use or negative statements find their way into the Redux labeling." The objection otherwise is overruled.

33. Exhibit P-165.06 through P-165.09 and P-165.11: Diagrams re: respiratory and circulatory systems, arteries and vasoconstriction vs. vasodilation.

Wyeth objects that these diagrams, especially those portions that reference the pulmonary arteries or pulmonary vasculature, do not relate in any way to heart valves or PH secondary to left-sided valvular heart disease, but rather that these portions of the diagrams implicate PPH. We will overrule the objection which is more properly raised with the presiding trial court judge.

Appendix D

E. Exhibits re: Promotion and Marketing of Redux.

34. Exhibit P-1: Time line of Pondimin and Redux Labeling Issues.

Wyeth objects to Exhibit P-1 on the ground that Plaintiff may use a portion of the exhibit to argue that Wyeth was motivated by sales and profits at the expense of drug safety in marketing Pondimin and Redux. We agree. We will therefore sustain the objection and order Ms. Clark to redact the exhibit to exclude: "Ron Notvest of AHP - need to craft labeling for promotional purposes."

Wyeth's separate objection to the language "Weintraub publication on long term use" will be overruled. The Weintraub study does not implicate a request for punitive damages.

35. Exhibit P-19: September 10, 1997 E-mail from Acri to Barton with attachment;

36. Exhibit P-20: Letter from Joseph sonk to Dr. Solomon Sobel dated August 28, 1997;

37. Exhibit P-57: July 17, 1996 Dear Doctor form letter;

38. Exhibit P-116: December 14, 1994 Madira Standard Letter;

Appendix D

39. Exhibit P-623: June 1994 Medical Affairs Information Letter from Wilson to A.H. Robins Sales Representatives re: Pondimin; and

40. Exhibit P-627: May 19, 1994 memo from Wilson to Buatti re: Pondimin Study Protocol No. 94-016-MA.

Wyeth objects to these exhibits because in its view plaintiff intends to use them to argue that it unlawfully and deceptively promoted Pondimin for combined use with phentermine, a use not approved by the FDA, or unlawfully promoted the drugs for other non-approved uses. The objections will be overruled because none of the exhibits appears on the surface to be relevant to a claim for punitive damages. A similar objection to Exhibit P-203 also will be overruled.

We emphasize, however, that the plaintiff will not be permitted to introduce evidence or make any argument relating to Wyeth's alleged illegal promotion of Pondimin and Redux or its alleged promotion to the extent that it was motivated by corporate profit and not safety.

41. Exhibit P-79: November 21, 1995 memo from Smith-Cox to Mahady and Essner re: Redux Market Research;

42. Exhibit P-92: July 31, 1995 memo from Notvest to Distribution re: Redux – Meeting at Klemtner;

Appendix D

43. Exhibit P-94: July 12, 1995 memo from Dolan to Deitch re: Dexfenfluramine Pre-Launch Marketing Plan;

44. Exhibits P-100 and P-586: June 9, 1995 memo from Notvest to List re: Meeting Minutes of the Redux Commercial Team Meeting;

45. Exhibit P-493: Updated distribution list page with Levy's September 2, 1996 handwritten notes re: Redux, and

46. Exhibit P-517: November 27, 1995 memo from Smith-Cox to Mahady re: Redux Market Research.

Wyeth objects to these exhibits on the ground that each is a marketing document that may be used to suggest that in marketing Pondimin and Redux Wyeth was motivated by sales and not drug safety. As we have explained, such evidence and argument can have no other purpose than to obtain punitive damages.

The objection to Exhibit P-79 is sustained, and the exhibit shall be redacted to remove the following language in the third full paragraph on bates stamped page AHP-Q-00057772: "The market is there waiting to be tapped if existing barriers and stigmas can be removed." The objection otherwise is overruled.

Appendix D

The objection to Exhibit P-92 is sustained because we believe that it is relevant only to a claim for punitive damages. The objections to Exhibits P-94 and P-493 are overruled. The exhibits do not relate in any way to a claim for punitive damages.

The objection to Exhibit p-100 is sustained such that plaintiff shall redact the following language on bates stamped page AHP-Q-00116746: "There is a clear need to continue to craft the labeling for promotional purposes (to be discussed at future team meetings)." The objection otherwise is overruled. The objection to Exhibit P-586, a duplicate of P-100, also is sustained.

The objection to Exhibit P-517 is sustained and the exhibit stricken. The exhibit relates to whether Wyeth was allegedly motivated by sales and profits in marketing and promoting Redux. In this regard, it is relevant only to punitive damages.

F. Exhibits re: Destruction of Documents, Concealment, Miscoding of information.

47. Exhibit P-1: Time line of Pondimin and Redux Labeling Issues; and

48. Exhibit P-12: December 30, 1997 fax from Hess with minutes of September 1997 meeting between the FDA, Wyeth and Interneuron.

Appendix D

Wyeth asserts that plaintiff intends to use exhibits P-1 and P-12 to suggest that it withheld or concealed certain information about the dangers of fen-phen. We will sustain the objections and order Ms. Clark to redact the following language from P-1: "Pondimin label changed. Only Adverse Event added is Alopecia (Hair Loss)." Exhibit P-12 shall be redacted by blacking out the following language on bates stamped page AHP-X-00009741: "it has to tell the public the truth and."

49. Exhibit P-13: Wyeth's 12/19/97 Response to FDA Form 483;

50. Exhibit P-14: 12/4/97 FDA Form 483; and

51. Exhibit P-16: 10/28/97 Day 29 minutes.

Wyeth objects to Exhibits P-13, P-14 and P-16 on the ground that each contains references to the overwriting of reports or miscoding of information. Because these topics go to the issue of wanton and malicious conduct, rather than negligence or strict liability, we will order plaintiff to redact the exhibits as follows:

Exhibit P-13: all references to the overwriting of documents;

Exhibit P-14: on bates stamped page AHP-W-00049958 the paragraph beginning with "On 3/7/97 manufacture control numbers" and ending with "different dates received by the manufacturer"; and

Appendix D

Exhibit P-16: all references, either direct or indirect to "miscoding" of information. In addition, bates stamped page AHP-W-00172070 shall be redacted by blacking out "commented, 'This place is driving me nuts,' and" in the second paragraph under the heading "9:30 A.M."

The objections otherwise are overruled.

52. Exhibit P-35: May 13, 1997 memo from Myers to Distribution re: Pondimin Safety Overview Meeting.

Wyeth objects to Exhibit P-35 because it references a need for separate safety overview meetings for Pondimin and Redux. It specifically contends that Ms. Clark intends to argue that Wyeth was attempting to conceal certain information about Redux from Interneuron, the technical sponsor of Redux at the FDA, by holding these separate meetings. We will overrule the objection. We reiterate, however, that Ms. Clark and her counsel are prohibited from offering evidence about or inquiring into the issue of concealment of information or destruction of documents. As we have explained, these topics relate directly to the issue of punitive damages.

53. Exhibit P-43: March 14, 1997 memo from Davis to G. Constantine re: Review of ADEs.

Wyeth maintains that plaintiff intends to use Exhibit P-43 to suggest that Wyeth intentionally miscoded Adverse Drug Events regarding valvular heart disease in an effort to

conceal information about the risks associated with the drugs. We will overrule the objection because the use anticipated by Wyeth is not apparent from the face of the document. As noted above, argument relating to the concealment of information or destruction of documents will be prohibited.

G. Miscellaneous Exhibits.

54. Exhibit P-32: E-Mail from Udicious to Bodner and Ballard dated June 11, 1997.

Because Exhibit P-32 does not in any manner implicate a claim for punitive damages, Wyeth's objection will be overruled.

55. Exhibit P-38: April 9, 1997 E-Mail from Patricia Acri to Davis re: Pondimin Label - Reply.

Wyeth objects on the basis that Exhibit P-38 relates to Pondimin and medical conditions other than valvular heart disease. We believe that the trial court is in a better position to rule on the objection to the proffered exhibit. We therefore will overrule the objection.

56. Exhibit P-39: April 9, 1997 Pondimin Labeling Change Submission.

Wyeth contends that certain redactions in Exhibit P-39 demonstrate why information in other exhibits also should be redacted. We see no problem with the actual contents of

Exhibit P-39 and will overrule the objection. The exhibit does not on its face inject the issue of punitive damages.

57. Exhibit P-91: August 8, 1995 memo from Pascuzzi-Heacock to Minicozzi re: Pondimin Supply for Dr. Stunkard.

Wyeth asserts that Exhibit P-91 will be used to argue that it may have violated federal law and regulations in providing shipments of Pondimin to an investigator conducting clinical trials on the drug. We will sustain the objection because the exhibit clearly is relevant only to a claim for punitive damages.

58. Exhibit P-104: May 26, 1995 Request for New or Revised Product – Pondimin Specification.

Wyeth objects to Exhibit P-104 on the basis that the plaintiff will use it to insinuate that Wyeth sat on a label change for Pondimin so as not to hurt FDA approval of Redux. We will overrule the objection. The trial court will be in a better position to rule on the merits of this objection. We reiterate, however, that use of the exhibit along the lines suggested by Wyeth would constitute an effort to punish it for allegedly placing corporate profits above safety concerns.

59. Exhibit P-123: August 15, 1994 memo from Acri and May to List re: Draft Pondimin Labeling Revision concerning PPH;

60. Exhibit P-125: June 30, 1994 memo from Wilson to Acri re: Pondimin labeling and Precautions (with handwritten note);

61. Exhibit P-126: June 30, 1994 memo from Wilson to Acri re: Pondimin labeling and Precautions;

62. Exhibit P-127: June 27, 1994 memo from Wilson to Myers re: Pondimin/Labeling Considerations;

63. Exhibit P-128: June 24, 1994 memo from Myers to Wilson re: Pondimin/Labeling Considerations; and

64. Exhibit 231: June 27, 1994 memo from Wilson to Myers re: Pondimin/Labeling Considerations.

This series of exhibits deals with revisions to the so-called Pondimin "four case" label. The four cases refer to the number of cases of "pulmonary hypertension" that were reported in the labeling for Pondimin. Wyeth contends that these exhibits are punitive in nature because they (1) impermissibly reference PPH; (2) suggest that Wyeth downplayed, understated and withheld knowledge of the health risks associated with Pondimin; and (3) delayed changing the Pondimin label until Redux was approved. The objections will be overruled. None of the exhibits appears on the surface to be relevant to a claim for punitive damages. Moreover, we believe that the trial court will be in a better

position to rule on the admissibility of the proffered exhibit. We emphasize, however, that as long as plaintiff's reference to the exhibit does not include any reference to PPH or its devastating consequences, and is limited to pulmonary hypertension secondary to left-sided valvular heart disease, we will not prohibit the reference as suggestive of punitive damages.

The objection to Exhibit P-231 also will be overruled. Exhibit P-231 is a duplicate of P-127.

65. Exhibit P-130: June 15, 1994 memo from LeKein to DanKulich re: summary of Significant New Information on Pondimin.

Wyeth objects to the attached memo from Dr. Wilson on the basis that plaintiff is offering it to suggest that Wyeth lied to the federal Food and Drug Administration. We do not believe the exhibit relates to a claim for punitive damages. The objection therefore will be overruled.

66. Exhibit P-140: May 1992 Weintraub Studies.

We will overrule the objection to Exhibit P-140. The exhibit does not relate to a claim for punitive damages or connote more than negligence on the part of Wyeth.

67. Exhibit P-143: March 2, 1990 memo from McDermott to file re: Visit of Representatives of Servier on February 27, 1990.

We will overrule the objection to Exhibit P-143. We do not believe it relates to a claim for punitive damages.

68. Exhibit P-232: September 15, 1997 memo from Sonk to List re: Contact Report Pondimin NDA 16-618.

This exhibit addresses the response to additional reports of valvulopathy associated with combined fenfluramine/ phentermine (fen-phen) therapy. Wyeth objects that the following passage is punitive in nature: "Dr. Sobel closed by saying this additional information is of *very grave concern* to the FDA and ask that we do everything to have the appropriate parties at the meeting tomorrow" (emphasis added). We disagree and will overrule Wyeth's objection.

69. Exhibit P-245: September 5, 1997 E-Mail from Graham re: fen-phen Weekly Update with attachment.

Wyeth objects to Exhibit P-245 on the basis that it suggests malfeasance on the part of the company that goes beyond mere negligence. The objection will be sustained in part. The following language shall be redacted:

(a) "section 4 addresses growing concerns which Lanh and I have regarding the diligence of Wyeth-Ayerst in reporting to FDA"; "ARDS, hypoxia, SSRI lawsuit against surgeon"; and "2 deaths in this report" on bates stamped page FDA-000 12507;

(b) "He says he contacted Wyeth-Ayerst with his findings, and asked for financial support so that he could echocardiogram all his patients. According to Bowen, W-A has ignored him" on bates stamped page FDA-000 12508, and

(c) the first and last sentences in the final paragraph on bates stamped page FDA-000 12509.

70. Exhibit P-246: September 3, 1997 E-Mail from Michaelis to Olsen and Ballard re: staffing of Wyeth Safety Surveillance Department.

Wyeth contends that Exhibit P-246, which references the staffing of the Safety Surveillance Department with temporary employees, is being proffered to suggest that Wyeth was more concerned about its bottom line than product safety. Wyeth's objection will be overruled. We do not see how the contents relate to a claim for punitive damages.

71. Exhibit P-453: June 5, 1996 memo from Acri to Distribution List re: Pondimin Labeling Revision, and

72. Exhibit P-777: June 5, 1996 memo from Acri to List re: Pondimin Labeling Revision.

Wyeth objects to Exhibit P-453 on the grounds that it relates to the so-called four case label, which may reference cases of PPH. The objection will be overruled. The punitive character of the exhibit is not apparent on the surface of the document.

We will overrule a similar objection to Exhibit P-777, which appears to be a duplicate of Exhibit P-453.

73. Exhibit P-462: April 29, 1996 DHHS letter from Bilstad to Interneuron re: Application Approval for Dexfenfluramine.

On the face of Exhibit P-462, Wyeth did not assert an objection. Moreover, the alleged punitive nature of the exhibit is not apparent. Any objection therefore will be overruled.

74. Exhibit P-785: September 15, 1997 E- Mail from Lutwak to Palmer, Reb and Stockbridge re: Weight Loss Drugs.

Wyeth objects that Exhibit P-785, an internal FDA E-Mail issued around the time the diet drugs were pulled from market, is punitive on its face. We agree. Ms. Clark may not use the exhibit.

75. Exhibit P-788: May 20, 1998 JAMA article "Time to Act on Drug Safety."

We will sustain the objection to Exhibit P-788. We believe it contains certain references that can be used only for the purpose of inflaming the jury to punish Wyeth. For example, the article notes that "Each year prescription drugs injure 1.5 million people so severely they require hospitalization and 100,000 die, making prescription drugs a leading cause of death in the United States." The exhibit therefore shall be stricken.

Appendix D

76. Exhibit P-826: February 25, 1998 AHP Internal Letter from considine and Conklin to Stafford and Blount re: Excess Policy Coverage.

Wyeth contends that Exhibit P-826, a memorandum concerning excess insurance policy coverage, will be used by plaintiff to argue that it was motivated by a desire to maximize sales and profits in promoting the diet drugs. Ms. Clark's counsel has conceded that the exhibit relates to an alleged $70 million expenditure Wyeth made to establish and publish a body of scientific studies that could be used to defend it against claims for bodily injury. The exhibit specifically suggests that the expenditure could be reimbursed under terms of an excess insurance policy. We question whether the exhibit would be admissible on any ground since it deals with insurance. However, based on the representations made by plaintiff's counsel as to how this exhibit is relevant, we believe that it relates directly to the issue of punitive damages. The objection will be sustained and the exhibit stricken.

77. Exhibit P-832: Welcome to Redux. Wyeth has no objection based on the contents of the exhibit itself. Any objection therefore will be overruled.

H. Deposition Testimony

Wyeth also has objected on various grounds to certain portions of the proffered deposition testimony of Dr. Ian Ballard, Joseph N. Bathish, Dr. Jo Alene Dolan, Robert

Appendix D

Levine, Joseph Mahady, Amy Myers, Roberta W. Michaelis, Paul Minicozzi, Ronald R. Notvest, Axel K. Olsen, and Dr. Frederick S. Wilson, each of whom was a Wyeth officer or employee. The objections will be sustained and/or the testimony redacted as follows:

78. Deposition Testimony of Dr. Ian M. Ballard, Executive Director of the Safety Surveillance Division (Jan. 7, 1999).

    a. Page 62:6 - 63:11. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

    b. Page 70:12-16; page 73:4 - 74:17; page 75:16 - 77:7; page 77:24 - 78:1. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue; and

c. Page 79:19-22; page 80:7 - 81:3. The testimony will be excluded to the extent that the testimony relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue.

79. Deposition Testimony of Joseph Bathish, Vice President of Regulatory Affairs (Feb. 2-3, 1999).

a. Page 398:25 - page 399:5 (Feb. 3, 1999). Such testimony is relevant only to a claim for punitive damages;

b. Page 403:11-21 and page 409:10-13 (Feb. 3, 1999). Such testimony is relevant only to a claim for punitive damages; and

c. Page 391:2-8; page 394:20 - 395:4; page 399:6 - 400:10; page 409:22 - 410:16 (Feb. 3, 1999). The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension

secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue.

80. Deposition Testimony of Dr. Jo Alene Dolan, medical monitor for Pondimin and Redux (Jan. 14-15, 1999).

    a. Page 415:8 - 417:7; page 417:14-22; page 418:3-13; page 419:14 - 420:5; page 420:18 - 423:11; page 423:19 - 425:12; page 426:2 - 429:19; page 430:16 - 431:13; page 431:20 - 433:2; page 434:11 - 435:5; page 435:10 - 436:5; page 437:14-18; page 438:5-13; page 441:3 - 441:5; page 442:3-9; page 443:24 - 444:19 (all Jan. 15, 1999). The designated testimony relates to the alleged ghostwriting of articles;

    b. Page 209:8-20; page 220:11-18; page 235:17-23 (Jan. 14, 1998). Such testimony is relevant only to a claim for punitive damages or to inflame the jury to punish Wyeth;

    c. Page 95:6-23 (Jan. 14, 1999). The objection is sustained only to the extent that plaintiff argues that Wyeth deliberately miscoded reports or concealed information;

d. "and by that I mean legal and moral" on page 105:8-9 (Jan. 14, 1999). Such testimony is designed to punish Wyeth for its alleged "bad conduct";

e. "both legal and moral" on page 106:24 (Jan. 14, 1999). Such testimony is designed to punish Wyeth for its alleged "bad conduct";

f. Page 111:5-8 (Jan. 14, 1999). Such testimony deals with Wyeth's financial condition; and

g. Page 183:5-22; page 184:20-185:24; page 186:6-14; page 186:22-187:19; page 188:1- 20; page 188:22 -189:5; page 206:17 - 207:4; page 207:9-13; page 209:21 - 210:16; page 213:14-219:14; page 220:1-10; page 220:21-221:2; page 221:6-17; page 224:1-3; page 231:14-232:8 (Jan. 14, 1999). We sustain the objection to the extent that the testimony relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to

rule on the specifics of this particular issue.

81. Deposition Designations for *Amy Myers*, Safety Surveillance Manager for Pondimin (Oct. 14-15, 1998).

Page 79:20-25; page 80:17 - 81:9; page 263:14 -264:9; page 267:10 - 269:1; page 81:16; page 82:1-8; page 83:20-22; page 85:10 - 86:10; page 89:13-16; page 89:19 - 90:2; ; page 91:4-10; page 92:20 - 93:14; page 142:5-9; and page 142:17 - 143:24; page 144:7-9 (Oct. 14, 1998}; page 323:17-22 (Oct. 15, 1998). The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue.

82. Deposition Testimony of *Amy Myers* in Rocha v. AHP (Nov. 11, 1999).

a. Page 154:5 - 156:19. Such testimony connotes more than negligence and appears relevant only to a claim for punitive damages;

b. Page 156:20 - 157:6; page 159:16 - 160:5 and page 160:12-16. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

c. Page 160:6-11. This testimony is relevant only to inflame the jury to punish Wyeth;

d. Page 164.23 - 165:3. The designated testimony relates to the alleged destruction of information, which, as we have indicated above, goes directly to the issue of punitive damages; and

e. Page 172:2 - 174:10; page 174:20 - 176:20; and page 179:24 - 181:19; page 183:11 - 185:9; and page 190:2-4. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular, heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position

to rule on the specifics of this particular issue.

83. Deposition Testimony of Roberta W. Michaelis, Associate Director of Safety Surveillance (Nov. 16-17, 1998).

    a. Page 208:23-24; page 209:24-25; page 210:17-21; page 215:3-11; page 216:5- 6; page 219:15-20; page 220:8-10; page 221:7-8; page 221-17-20; page 222:10-11; page 223:19-20; page 227:10-12; page 228:11-12; page 229:15-16; page 230:14-15; page 231:19-20; page 232:21-23; page 233:21-22; page 235:14-19; page 236:8-9; page 237:13-14; page 238:16-17; page 239:22-23; page 240:16-17; page 243:3-4; page 244:2-3; page 244:16-20; page 246:21-22; page 249:5-12; page 250:5-8; page 251:4-8 (Nov. 16, 1998). While the failure to report to the FDA is a permissible line of inquiry, plaintiff may not argue that Wyeth's failure to do so was deliberate or an act of deception;

    b. Page 434:25 - 435:19 (Nov. 17, 1998). This testimony will be excluded to the extent that it relates

to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue; and

c. Page 502:25 - 503:19 and page 505:17 - 506:2 (Nov. 17, 1998). This testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue.

84. Deposition Testimony of *Paul Minicozzi*. medical monitor for Pondimin (Jan. 5-6, 1999).

a. Page 202:22-24, page 204:9-22, page 205:11-20 and page 206:5-19. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The

trial court is in a better position to rule on the specifics of this particular issue;

b. Page 363:22 - 366:22; page 368:13 - 369:2; page 373:7-24; page 375:7 - 376:2. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

c. Page 408:7-19; page 409:1-11; page 413:8-16; page 419:20 - 422:6. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

d. Page 432:8-22; page 435:1-4; page 435:16 -436:5; page 436:23 - 437:10. The testimony will be excluded to the extent that it relates

to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue; and

e. Page 521:11-19; page 522:1 - 525:24; page 526:11-17; page 528:1-10. This testimony will be excluded because it clearly is relevant only to a claim for punitive damages.

85. Deposition Testimony of *Ronald R. Notvest*, Senior Product Manager in Marketing Department (Oct. 26-27, 1998).

a. Page 40:21 - 41:7. Such testimony relates to Wyeth's financial condition;

b. Page 50:4-25. Such testimony is relevant only to a claim for punitive damages, because it portrays Wyeth as downplaying risks to maximize sales and profits of the diet drugs;

c. Page 30:19 - 82:15; and page 82:24 - 83:16. The designated testimony is designed to inflame the jury and

punish Wyeth by focusing on Wyeth's alleged immoral and irresponsible conduct;

d. Page 86:11-17. Such testimony is relevant only to a claim for punitive damages;

e. Page 77:19-24. Such testimony is relevant only to a claim for punitive damages;

f. Page 83:18 - 84:4. Such testimony is relevant only to a claim for punitive damages;

g. Page 80:9-18; page 84:6-10; page 84:16-24; page 86:6-10; page 87:5-6; and page 87:11 (to the extent not stricken as discussed above). The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

h. Page 402:22 - 403:1 and 411:13-23; page 412:6-22. Such testimony is relevant only to a claim for punitive damages;

Appendix D

i. Page 401:3-13; page 402:7-9; page 402:12-21; page 403:12-14; page 410:10- 12. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

j. Page 414:5-9; page 415:21 - 416:1; page 416:9-15; page 417:18 - 419:8. The designated testimony relates to a claim for punitive damages; and

k. Page 419:18-21; page 419:25 - 420:25, The designated testimony focuses on Wyeth's alleged promotion of fen-phen at the expense of safety and therefore is relevant only to a claim for punitive damages.

Appendix D

86. Deposition Testimony of *Axel K. Olsen*, Director of Worldwide Safety Surveillance and Medical Operations (July 28-29, 1998 and Oct. 22-23, 1998).

    a. Page 268:17 - 269:6; and page 269:25 -271:18. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left- sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

    b. Page 272:2-7. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left- sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

    c. Page 281:2-9, The proffered testimony is relevant only to a claim for punitive damages;

    d. Page 307:23 - 308:3 and 311:21 - 312:1. The testimony will be

excluded to the extent that it relates to conditions other than left- sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

e. Page 743:10-11; page 748:20 - 749:5; page 750:23 - 751:7; page 752:9-19; page 754:15- 19. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left- sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

f. Page 822:5-7 and page 822:15-19. The testimony will be excluded to the extent that it relates to conditions other than left- sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue; and

g. Page 822:24 - 823:3. The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue.

87. Deposition Testimony of *Frederick S. Wilson, M.P.*, medical monitor for Pondimin (Nov. 18-19, 1998).

a. Page 49:13 - 50:1 (Nov. 18, 1998). The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

b. Page 554:6 - 555:1; page 555:10 - 556:16 and page 557:6-20 (Nov. 19, 1998). Such testimony is relevant only to a claim for punitive damages;

c. Page 553:9 - 554:5; page 555:2-9; page 556:17 - 557:5 (Nov. 19, 1998). The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

d. Page 148:4-12 (Nov. 18, 1998). Such testimony suggests that Wyeth was motivated by sales and profits and not safety in promoting Pondimin;

e. Page 384:4 - 385:8; page 385:16 - 386:3; page 418:11 - 419:15; page 422:23 - 423:9; and page 423:18 - 425:6 (Nov, 19, 1998). The testimony will be excluded to the extent that it relates to conditions other than left- sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue;

f. Page 482:2-17; page 483:7-15, page 484:16 - 485:2; and page 486:12-23 (Nov. 19, 1998). The designated testimony suggests that Wyeth sanctioned the promotion of Pondimin for uses not approved by the FDA. We believe it is relevant only for punitive purposes; and

g. Page 493:13 - 495:15; page 496:3-23; page 498:15 - 499:3; page 513:19 - 525:16 (Nov. 19, 1998). The testimony will be excluded to the extent that it relates to conditions other than left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease. The trial court is in a better position to rule on the specifics of this particular issue.

The objections to the deposition designations of Robert Levine and Joseph Mahady, as well as the remaining designations of the witnesses named above, are overruled because they do not pertain to a claim for punitive damages.

IV.

We believe that we have provided the parties in Clark with sufficient guidance so as to minimize the emergence of evidence, arguments, or statements related to the issue of

punitive, exemplary, or multiple damages, either in fact or in name. Obviously, we will not be present at the trial and cannot rule in advance on every possible contingency. Again, we emphasize that the prohibition in § IV.D.3.C of the Settlement Agreement against non-compensatory damages overrides any contrary or inconsistent state evidentiary, procedural, or substantive rule of law. We are confident that the state trial judge will see to it that the terms of the Nationwide class Action Settlement Agreement will be upheld in accordance with this PTO. With respect to any evidence or subject which we have not ruled out of the case, it will, of course, be within the province of the state judge to determine admissibility. For example, issues of hearsay, relevance, and undue prejudice will still be matters for the state judge with respect to any proffered evidence not specifically excluded by this court because of the terms of the Settlement Agreement.

V.

Hamid R, Jalali, D.O., Ms. Clark's treating physician, is also a defendant in the Clark case in addition to Wyeth. Plaintiff or her counsel will not be permitted to circumvent this court's rulings by seeking to introduce any forbidden evidence or make any forbidden statement or argument on the ground that it is directed solely against him. So to avoid any misunderstanding, the injunction to be entered applies equally with respect to any claim against Dr. Jalali.

Appendix D

VI.

Finally, we note that George Fleming, Esquire, whom we held in contempt in PTO 2717, has now withdrawn his appearance in the Clark case, although lawyers in his firm are still participating. Thus, the injunctions against Mr. Fleming himself are moot. Mike O'Brien, Esquire has entered his appearance in Mr. Fleming's stead and has submitted an affidavit of compliance as required under PTO 2717. Because of the obdurate conduct of Mr. Fleming which has deeply infected this case and in an effort to move the case forward, we are providing the parties herein with further specificity as to what is enjoined. Accordingly, we will vacate PTO 2625 and PTO 2717 in light of the current circumstances and replace them with the present PTO. Ms. Clark may now go forward with her trial consistent with what we have ordered herein. Should it be called to our attention that any party or attorney has violated the superseding PTO at the trial, we will not hesitate to take whatever remedial or punitive measures that are appropriate.

Appendix D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MDL Docket No. 1203

CIVIL ACTION NO. 99-20593

IN RE: DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO

SHEILA BROWN, et al.,

v.

AMERICAN HOME PRODUCTS CORPORATION

PRETRIAL ORDER NO. 2828

AND NOW, this 8th day of April, 2003, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) Pretrial Order No. 2625 and Pretrial Order No. 2717 are VACATED;

(2) the plaintiff Clara Clark, her agents, attorneys, and derivative claimants are ENJOINED in the case of *Clark v. Wyeth et al.*, No. B020182-C, pending in the District Court

of Orange County, Texas, from introducing any evidence, making any statement before or argument to the court or jury, related directly or indirectly to:

(a) punitive, exemplary or multiple damages, however described;

(b) malicious, wanton or other similar conduct of Wyeth, however described; and

(c) any medical condition of plaintiff caused by Wyeth other than left-sided mitral valve regurgitation or pulmonary hypertension secondary to mitral valve regurgitation;

(3) without limitation as to the scope of the injunction set forth in ¶ 2, plaintiff Clara Clark, her agents, attorneys, and derivative claimants are ENJOINED in the case of *Clark v. Wveth et al.*, No. B020182-C, pending in the District Court of Orange County, Texas, from introducing any evidence or making any statement before or argument to the court or jury related directly or indirectly to the following subjects:

(a) Wyeth's profits, size or financial condition;

(b) the amount or size of Wyeth's sales of diet drugs or other products,

(c) Wyeth's marketing or promotion of diet drugs to the extent that Wyeth placed marketing or promotion ahead of health or safety concerns;

(d) any deception or any destruction, hiding, overwriting, or deliberate miscoding of documents or information by Wyeth;

(e) any involvement by Wyeth in the ghostwriting of articles;

(f) primary pulmonary hypertension;

(g) neurotoxicity; and

(h) any other disease, illness or condition or persons suffering from any other disease, illness or condition caused by Redux or Pondimin except for left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease;

(4) without limitation on the scope of the injunction set forth in ¶¶ 2 and 3, the plaintiff, her agents, attorneys, and derivative claimants are ENJOINED in the case of *Clark v. Wyeth et al.*, No. B020182-C, pending in the District Court of Orange County, Texas, from introducing the challenged exhibits (or portions of exhibits) and challenged deposition testimony (or portions of deposition testimony) or making any statement before or argument to the court or jury related directly or indirectly to the said exhibits and deposition testimony or the contents thereof, except as allowed in the Memorandum portion of this PTO; and

(5) the parties shall deliver forthwith to the state trial judge a copy of this Memorandum and Pretrial Order.

BY THE COURT:

s/ Harvey Bartle
Harvey Bartle, J.

APPENDIX E — MEMORANDUM AND PRETRIAL ORDER NO. 2717 OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA DATED JANUARY 29, 2003

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MDL Docket No. 1203

CIVIL ACTION NO. 99-20593

IN RE: DIET DRUGS
(PHENTERMINE, FENFLURAMINE,
DEXFENFLURAMINE) PRODUCTS
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS CORPORATION

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, J. January 29, 2003

In this multi-district litigation involving the diet drug "fen-phen," we have before us Wyeth's motion for further injunction and for civil contempt and sanctions against George M. Fleming, Esquire of Houston, Texas.

Appendix E

On October 16, 2002, this court issued an order enjoining plaintiff class member Clara Clark and her attorney George M. Fleming from injecting the issue of punitive damages into her lawsuit against Wyeth pending in the District Court of Orange County, Texas under the caption *Clark v. Wyeth, et al.*, No. B020182-C. *See* Memorandum and Pretrial Order ("PTO") No. 2625 (Oct. 16, 2002). We did so because the Nationwide Class Action Settlement, approved by the court, prohibits intermediate opt-out plaintiffs, such as Ms. Clark, from seeking "punitive, exemplary or any multiple damages" against released parties, including Wyeth. Settlement Agreement § IV.D.3.c; *see* PTO 2625.

On December 11, 2002, we issued a similar injunction involving *Smart v. American Home Prods. Corp.*, No. 02-04-40259-CV, an action pending in the state court in Jim Wells County, Texas. *See* PTO 2680 (Dec. 11, 2002). The same George Fleming was the attorney for the plaintiff class member in that case. *See id.*

The injunction in *Clark* states in relevant part:

> (2) the plaintiff Clara Clark, her agents, attorneys, and derivative claimants are ENJOINED in the case of *Clark v. Wyeth et al.*, No. B020182-C, pending in the District court of Orange County, Texas, from introducing any evidence or making any statement before or argument to the court or jury related directly or indirectly to (a) punitive, exemplary or multiple damages, however described; and (b) malicious, wanton or other similar conduct of Wyeth, however described . . . .

Appendix E

The *Clark* action, we are told, is now scheduled for trial to begin on Monday, February 3, 2003, only a few days from now.

Instead of ceasing his efforts to introduce the issue of punitive damages into the *Clark* case after we filed PTO 2625, Mr. Fleming has acted as if the Order does not exist. His current pretrial submissions in *Clark* demonstrate his intention to permeate the trial with evidence and argument designed to inflame the jury to award punitive damages in effect if not in name. For example, Plaintiff's Fourth Amended Designation of Expert Witnesses, filed on January 10, 2003, identifies numerous potential conduct-related topics, including that:

> Wyeth failed to establish and maintain records;
>
> Wyeth failed to disclose information to the public received or otherwise obtained with respect to the safety and effectiveness of fenfluramine/dexfenfluramine;
>
> Wyeth violated numerous provisions of the code of Federal Regulations (C.F.R.);
>
> Wyeth entirely failed to report serious and unexpected adverse drug experience information; [and]

Appendix E

> The conduct of [Wyeth] under the circumstances was a gross departure from accepted standards which apply to pharmaceutical firms such as [Wyeth] in this case.

See Plaintiff's Fourth Amended Designation of Expert Witnesses at 12-13, 16.

Plaintiff's amended trial exhibit list, also filed on January 10, 2003, likewise illustrates counsel's motive to infect the trial with improper bad conduct evidence concerning Wyeth. The exhibit list includes sections of the Code of Federal Regulations, United States Code and the *Texas Penal Code* that plaintiff contends Wyeth has violated, as well as documents concerning Wyeth's financial condition. Furthermore, plaintiff has identified documents relating to Wyeth's alleged "manipulation" of the FDA and its alleged efforts to use lobbying to remove the diet drugs from the list of controlled substances. The inclusion of this conduct-related evidence can only be relevant to punitive damages which, of course, are forbidden.

At a pretrial hearing in *Clark* held on January 23, 2003, only a few days ago, the Texas state trial judge also recognized that Mr. Fleming was seeking punitive damages with his submissions. Judge Powell stated on the record:

> . . . I'm very interested in a very [sic] returning a fair verdict that is an approximation of the damages and not a result of them [the jury] being incensed.

> And to some degree, Mr. Fleming, you have invited all of this on yourself by loading this record up with stuff that is very relevant to an award of exemplary damages and some of which is relevant on the issue of negligence.

January 23, 2003 Hearing Transcript at 16:13-21.

Mr. Fleming has engaged in a pattern of evasion and lack of candor with this court. After the entry of the October 16, 2002 injunction in *Clark*, Wyeth advised the court that Mr. Fleming was engaging in similar improper conduct in *Smart*. We immediately told Mr. Fleming in open court that we would not tolerate in *Smart* what we had enjoined in *Clark*. Mr. Fleming assured the court that he was not engaging in such conduct. Shortly thereafter, when the court was presented with Wyeth's motion to enjoin in *Smart* and had the facts before it, it was clear that Mr. Fleming had made misrepresentations to this court and was in fact doing in Smart exactly what he had done in *Clark*. He has persisted in his circumvention of this court's October 16, 2002 Order in Clark by withdrawing certain submissions but maintaining or substituting others of equal kind in the hope of inflaming the jury to award more than compensatory damages.

The contumacious behavior of Mr. Fleming is all the more flagrant since Wyeth has consented to the entry of judgment simply upon proof of (1) its drug Redux as the cause in fact of Ms. Clark's alleged mitral regurgitation; and (2) her damages, if any. Wyeth has conceded for purposes of this case that it was the manufacturer of the drug in question, that it was negligent and its product defectively designed, and that injury from this defective product was foreseeable.

Appendix E

In order to find a person or party in civil contempt, it must be established by clear and convincing evidence that (1) there is a valid court order; (2) the person or party has knowledge of said order; and (3) he or she has refused to obey the order. *See Roe v. Operation Rescue*, 54 F.3d 133, 137 (3d Cir. 1995).

First, PTO 2625 is a valid Order. It is well established that we have authority to issue orders to protect or effectuate our judgments in overseeing this Nationwide Class Action Settlement. *In re Prudential Ins. Co. of Am.*, 261 F.3d 355, 364 (3d Cir. 2001). The Settlement Agreement, as approved in PTO 1415, explicitly prohibits any intermediate opt-out plaintiff, such as Ms. Clark, from seeking punitive or exemplary damages. See Settlement Agreement § IV.D.3.c. In addition, Mr. Fleming concedes he read PTO 2625 shortly after it was handed down as he knew about PTO 2680, shortly after it was handed down in the *Smart* case.

Finally, as to the third element in any civil contempt proceeding, it is absolutely clear that Mr. Fleming has refused to obey PTO 2625. Although he argues that he is not seeking punitive damages, his actions belie his words. His conduct is nothing but a blatant assault aimed at flouting the Order of this court and undermining the carefully crafted Nationwide class Action Settlement Agreement. Memorandum and PTO 2625 and Memorandum and PTO 2680 have had no effect on him. As we have said on other occasions, a party or lawyer may not hide behind the procedural, evidentiary, or substantive law of a state in order to evade PTO 1415 and the proscription in the Nationwide Class Action Settlement Agreement against "punitive,

exemplary, or multiple damages." If George Fleming is allowed to proceed as he wishes here, others will not be far behind. The floodgates will open, and the prohibition against punitive damages in the court approved Settlement Agreement will be nothing but a dead letter, with potentially dire consequences for the settlement and the ability of the thousands of class members to obtain compensation. This court has a special responsibility to prevent this outcome from happening.

We find by clear and convincing evidence that George M. Fleming, Esquire is in civil contempt of PTO 2625. Our goal is to bring about compliance so that Ms. Clark may promptly have her day in court consistent with the terms of the Settlement Agreement. The Supreme court and our Court of Appeals have emphasized that courts have broad power in fashioning a remedy for civil contempt. *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 193-94 (1949); *In re Arthur Treacher's Franchisee Litig.*, 689 F.2d 1150, 1158-59 (3d Cir. 1982).

In order to achieve our goal, we will enjoin the plaintiff, George M. Fleming, Esquire, and their agents and attorneys from proceeding to trial in *Clark* unless and until Mr. Fleming satisfies this court that he is and will remain in compliance with this court's PTO 2625. Mr. Fleming must submit and obtain court approval of a statement under oath that with respect to Wyeth's conduct he will not inject into the case any evidence, statement, or argument, directly or indirectly, that connotes more than simple negligence or defective design without fault on the part of Wyeth. The statement must also declare that he will not introduce at the trial any reference to

Wyeth's size, financial condition, or worth. He must also include as part of his statement his trial exhibits, witness list, and points for charge. Concededly, it will be for the state trial judge to decide on the exact contours of the evidence, arguments, and statements to be presented to the court and to the jury. Whether and to what extent, for example, Ms. Clark may seek to prove simple negligence or defective product design, despite the admissions or offer of partial judgment by Wyeth, is a matter for the Texas court. Nonetheless, it is our role to prevent the injection of anything related to punitive, exemplary or multiple damages. Our review will only be to this extent. While we are loath to become involved in such detail, the obdurate behavior of Mr. Fleming leaves us no alternative if the terms of the Settlement Agreement are to be upheld.

Wyeth will have seven business days after receipt of Mr. Fleming's statement to file with this court its position on whether Mr. Fleming's statement is in compliance with PTO 2625. The court will vacate the injunction if it is satisfied that Mr. Fleming is obeying and will obey PTO 2625. Should Mr. Fleming proceed to trial after the lifting of the injunction and violate PTO 2625, we will not hesitate to take further remedial or punitive action as necessary.

It is a sad day for the court to hold a member of the bar in civil contempt. We do so reluctantly. Unfortunately, we have no other choice.

Appendix E

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MDL Docket No. 1203

CIVIL ACTION NO. 99-20593

IN RE: DIET DRUGS
(PHENTERMINE, FENFLURAMINE,
DEXFENFLURAMINE) PRODUCTS
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS CORPORATION

PRETRIAL ORDER NO. 2717

AND NOW, this 29th day of January, 2003, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the motion of Wyeth for further injunction and for sanctions to enforce PTO 2625 against class member Clara Clark and her counsel George M. Fleming, Esquire is GRANTED;

(2) as a result of civil contempt of this court's PTO 2625 by plaintiff's attorney, George M. Fleming, Esquire, plaintiff Clara Clark, her attorney George M. Fleming, Esquire, and their agents and attorneys are hereby ENJOINED from commencing the trial of *Clark v. Wyeth et al.*, No. B020182-C, pending in the District Court of Orange County, Texas, unless and until said George M. Fleming, Esquire satisfies this court that he is and will remain in compliance with PTO 2625. Specifically, before they may proceed to trial, George M. Fleming, Esquire must submit and obtain this court's approval of a statement under oath that he will obey PTO 2625. That statement must declare that with respect to Wyeth's conduct he will not inject into the case any evidence, statement, or argument, directly or indirectly, that connotes more than simple negligence or defective design without fault. The statement must also declare that he will not introduce at the trial any reference to Wyeth's size, financial condition, or worth. He must also include as part of his statement his trial exhibits, witness list, and points for charge;

(3) Wyeth shall have seven business days after receipt of Mr. Fleming's statement to file with this court its position on whether Mr. Fleming's statement is in compliance with PTO 2625; and

(4) Wyeth shall forthwith furnish a copy of this Memorandum and Order to the trial judge in the District Court of Orange County, Texas.

BY THE COURT:

s/ Harvey Bartle, J.

APPENDIX F — MEMORANDUM AND PRETRIAL ORDER NO. 2680 OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA DATED DECEMBER 11, 2002

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MDL DOCKET NO. 1203

CIVIL ACTION NO. 99-20593

IN RE: DIET DRUGS
(PHENTERMINE, FENFLURAMINE
DEXFENFLURAMINE) PRODUCTS
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS CORPORATION

MEMORANDUM AND PRETRIAL ORDER NO. 2680

Bartle, J. December 11, 2002

Before the court is the motion of Wyeth[1] for an Injunction to Enforce the Nationwide Class Action Settlement

1. Wyeth was previously known as American Home Products Corporation.

Appendix F

Agreement Against Class Member Linda Smart and Her Counsel. Wyeth seeks expedited consideration.

Linda Smart has pending an action against Wyeth in the District Court of Jim Wells County, Texas arising out of alleged injuries she suffered from ingesting Pondimin, a weight loss drug. *See Smart v. American Home Prods. Corp.*, No. 02-04-40259CV. At the time of the argument on the pending motion, we were told that the trial was imminent.

It is undisputed that Ms. Smart, an intermediate opt-out, remains a class member governed by the Nationwide Class Action Settlement involving the diet drugs collectively known as fen-phen. Ms. Smart is represented in her lawsuit by George Fleming, Esquire of Fleming & Associates, LLP in Houston, Texas.

The Settlement Agreement bars Ms. Smart and any other class member who exercises an intermediate or back-end opt-out from seeking "punitive, exemplary, or any multiple damages" against Wyeth in any fen-phen lawsuit. See Settlement Agreement §§ IV.D.3.c and IV.D.4.c. Wyeth contends that despite this prohibition, plaintiff is seeking such damages. Accordingly, it requests injunctive relief to enforce the Settlement Agreement which binds Ms. Smart. This court, which oversees the settlement, has power to do so. *See* Pretrial Order No. 1415; *In re: Prudential Ins. Co. of Am. Sales Practice Litig.*, 261 F.3d 355, 367-68 (3d Cir. 2001).

Mr. Fleming, counsel to Ms. Smart, is no stranger to the issue before us. Only several months ago Wyeth filed a nearly

identical motion involving another class member represented by Mr. Fleming in a case pending against Wyeth in the District Court of Orange County, Texas. *See Clark v. Wyeth*, No. B020182-C (orange County, Texas). After a hearing, we entered the following injunction against Ms. Clark and her counsel which states in relevant part:

> (2) the plaintiff Clara Clark, her agents, attorneys, and derivative claimants are ENJOINED in the case of *Clark v. Wyeth et al.*, No. B020182-C, pending in the District Court of Orange County, Texas, from introducing any evidence or making any statement before or argument to the court or jury related directly or indirectly to (a) punitive, exemplary or multiple damages, however described; and (b) malicious, wanton or other similar conduct of Wyeth, however described; and
>
> (3) the plaintiff, her agents, attorneys, and derivative claimants are ENJOINED in the case of *Clark v. Wyeth et al.*, No. B020182-C, pending in the District Court of Orange County, Texas, from introducing any evidence or making any statement before or argument to the court or jury related directly or indirectly to any medical condition of plaintiff caused by Wyeth other than mitral valve regurgitation or pulmonary hypertension secondary to mitral valve regurgitation.

Pretrial Order No. 2625 (Oct. 16, 2002).

Appendix F

Despite the injunction in *Clark*, Mr. Fleming persists in seeking to inject the issue of punitive damages into the *Smart* action in direct violation of the Settlement Agreement, it is true, as in *Clark*, that Mr. Fleming is not specifically requesting a state court to charge on punitive damages or the jury to return an award denominated as such. Nonetheless, what he is not doing in name, he is doing in substance. At a hearing on November 12, 2002, the state trial judge recognized counsel's dubious tactic. The judge accurately observed, "He wants for the jury to hear the entire story and try to get them [riled][2] up." 11/12/02 Tr. at 101. We will not recite in their entirety Mr. Fleming's not so subtle efforts to circumvent a precedent of this court which is directly on point. A few examples from the inflammatory charge he has submitted to the Texas court will suffice:

> Wyeth has known the serious side effects of fenfluramine and/or dexfenfluramine for a substantial period of time. These side effects were known or should have been known to Wyeth at the time that it marketed the drugs to the public based on, among other things, medical evidence of dangerous and potentially fatal side effects from the use of the drugs in Europe and elsewhere, as detailed below. Wyeth did not, however, conduct adequate testing to establish the safety of the drugs before marketing them. Rather, Wyeth aggressively marketed the drugs and promoted their use, both individually and in combination with other drugs, while downplaying evidence of

2. The transcript contains the word "wild."

the serious and potentially fatal side effects that consumers of these drugs could face.

. . .

The marketing program as a whole, by affirmative misrepresentations and omissions, falsely and fraudulently sought to create the image and impression that the use of fenfluramine, both individually and/or in combination with phentermine, was safe for human use . . . .

Wyeth purposefully downplayed and understated the health hazards and risks associated with fenfluramine and/or dexfenfluramine.

Wyeth falsely and fraudulently concealed relevant information from doctors and potential fenfluramine and/or dexfenfluramine users regarding the safety of fenfluramine and/or dexfenfluramine.

. . .

Further, Wyeth failed to conduct or fund any studies or research regarding the long-term safety of the fenfluramine drug, Pondimin.

. . .

Wyeth continued to promote Pondimin after learning of the extreme danger associated with it.

Appendix F

Wyeth continued to promote Pondimin knowing the drug had no beneficial use . . . .

Even after it knew of the danger Wyeth did not remove Pondimin from the market and did not do any further testing of the drug. Instead, Wyeth continued to market the drug to prescribing physicians like the physician that prescribed the diet drugs to the plaintiff in this case.

. . .

Further, Wyeth destroyed, removed and concealed written evidence and/or intentionally misrepresented evidence supporting the association between valvular heart disease and AHP's fenfluramine (Pondimin) and dexfenfluramine (Redux).

. . .

Further, Wyeth engaged in a cover up and fraudulently destroyed, removed and concealed written documents from FDA investigators, physicians and their patients, including the plaintiff, in an illegal attempt to hide Wyeth knowledge of the association between pulmonary hypertension and valvular heart disease and Pondimin and Redux. Wyeth attempt to hide their knowledge was accomplished by the deletion, destruction, miscoding and re-coding of Adverse Drug Event reports . . . .

Appendix F

So as to remove any doubt, the above excerpts and others similar to them would clearly violate the injunction in *Clark* (and the injunction to be entered in this case) against evidence or argument "related directly or indirectly to "malicious, wanton or other similar conduct of Wyeth however described."

Because of certain admissions by Wyeth, the state court has entered a "partial interlocutory default judgment." The issues to be tried are limited to

> (1) whether Plaintiff has the condition of mitral valve regurgitation as defined in the Nationwide Class Action Settlement Agreement, and
>
> (2) whether her exposure to Pondimin was the cause in fact of her developing her claimed condition of mitral valve regurgitation as defined in the Nationwide Class Action Settlement Agreement, and
>
> (3) whether and to what extent Plaintiff sustained damages as a result of mitral valve regurgitation.

Plaintiff contends that it is necessary to read the proposed charge to the jury in order to establish causation between Ms. Smart's taking of Pondimin and her injuries. This argument is totally without merit. It is not disputed that Wyeth manufactured and marketed this drug. Whether or not Wyeth engaged in the type of conduct which would give rise to punitive damages absent the bar in the settlement Agreement has nothing whatever to do with whether Pondimin caused

her mitral valve regurgitation. The jury will decide the issue of causation based on the testimony of medical experts, irrespective of the nature of Wyeth's behavior, be it wanton or innocent or somewhere in between. Beyond any doubt, as the state trial judge recognized, the real purpose of the proposed charge is to inject the issue of punitive damages into this case, and that violates § IV.D.3.c of the Nationwide Class Action Settlement Agreement.

Mr. Fleming makes a number of other arguments all relying on the law of Texas. In effect, he contends that if he is not allowed to inject the elements of Wyeth's alleged wanton conduct, his client's rights under state law will suffer. At no point, however, has he argued that Ms. Smart would not be able to recover the full amount of compensatory damages allowed under Texas law if the requested relief is granted to Wyeth.

We reiterate a few salient points. The terms of the Settlement Agreement approved by this court in Pretrial Order No. 1415 prevail over state law, whether the latter is characterized as substantive, evidentiary, or procedural. The Settlement Agreement unequivocally forbids an intermediate or back-end opt-out plaintiff, who remains a class member, from seeking punitive damages. There are no exceptions for conflicting state law. Nor does the Settlement Agreement contain an exception to allow a class member to introduce into evidence or to argue the elements of a punitive damage claim on the condition that he or she does not specifically request punitive damages by name. Such a reading would create a giant loophole, having the effect of nullifying the prohibition of the court approved Settlement Agreement

"against punitive, exemplary, or any multiple damages." See Settlement Agreement § IV.D.3.c.

An injunction follows.[3]

---

3. Wyeth has requested that this court incorporate into its injunction the "partial interlocutory default judgment" entered by the state court judge. We decline to do so. Our role is to enforce the provisions of the Settlement Agreement prohibiting Ms. Smart and her counsel from pursuing punitive damages. We will not otherwise interject ourselves into the management of the state court action.

Appendix F

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MDL DOCKET NO. 1203

CIVIL ACTION NO. 99-20593

IN RE: DIET DRUGS
(PHENTERMINE, FENFLURAMINE
DEXFENFLURAMINE) PRODUCTS
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS CORPORATION

PRETRIAL ORDER NO. 2680

AND NOW, this 11th day of December, 2002, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the motion of Wyeth for expedited consideration is GRANTED;

(2) the motion of Wyeth for an injunction to enforce the Nationwide Class Action Settlement Agreement against

class member Linda Smart and her counsel, George Fleming, Esquire is GRANTED; and

(3) the plaintiff Linda Smart, her agents, attorneys, and derivative claimants are ENJOINED in the case of *Smart v. American Home Prods. Corp.*, No. 02-04-40259-CV pending in the District Court of Jim Wells County, Texas, from introducing any evidence or making any statement before or argument to the court or jury related directly or indirectly to (a) punitive, exemplary or multiple damages, however described; and (b) malicious, wanton or other similar conduct of Wyeth, however described.

BY THE COURT:

s/ Harvey Bartle, J.

APPENDIX G — MEMORANDUM AND PRETRIAL ORDER NO. 2625 OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA DATED OCTOBER 16, 2002

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MDL DOCKET NO. 1203

CIVIL ACTION NO. 99-20593

IN RE: DIET DRUGS
(PHENTERMINE, FENFLURAMINE
DEXFENFLURAMINE) PRODUCTS
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS CORPORATION

MEMORANDUM AND PRETRIAL ORDER NO. 2625

Bartle, J. October 16, 2002

Wyeth, previously known as American Home Products Corporation, has moved for enforcement of Pretrial Order ("PTO") No. 1415 which approved the class action settlement in this massive litigation involving the diet drug "fen-phen."

Specifically, Wyeth seeks to prevent class member Clara Clark from proceeding with certain claims as the plaintiff in a lawsuit pending against it in the District Court of Orange County, Texas, *Clark v. Wyeth et al.*, No. B020182-C. The case was scheduled to go to trial on October 21, 2002.[1] Wyeth contends that she is asking for punitive damages and pursuing a settled claim in violation of the Settlement Agreement.

Ms. Clark has exercised her right of an intermediate opt-out and has elected to sue Wyeth for damages in the tort system rather than obtain benefits from the AHP Settlement Trust. Despite her opt-out, it is important to emphasize that she remains a member of the class who is bound by the terms of the Settlement Agreement.

In return for Wyeth's waiving the statute of limitations for those class members such as Ms. Clark who exercise either an immediate or back-end opt-out, the Settlement Agreement provides that such class members may not seek "punitive, multiple, or exemplary damages" against any released party including Wyeth. See Pretrial Order No. 1415 at 58-59. A plaintiff is therefore limited to compensatory damages in any lawsuit. Admittedly, Ms. Clark does not use the words "punitive, multiple, or exemplary damages" in her pleadings in the Texas state court, and her proposed charge to the jury is likewise devoid of any instruction to this effect. This does not, however, end our analysis.

Plaintiff's "Bench Brief," which she recently filed with

---

1. Following oral argument, counsel for Wyeth notified this court that the trial had been continued until February, 2003.

the state court, summarizes the case she intends to present to the jury. It is replete with statements leading ineluctably to the conclusion that such punitive damages are being sought, even though not by that name. For example, it gives notice that she intends to introduce evidence that "tens of thousands of people were injured as a result of taking [Wyeth's] diet drugs, that "[Wyeth] acted maliciously and with callous indifference . . ." and that "[Wyeth's] wrongdoing is of staggering proportion." Plaintiff's Bench Brief at 1, 6. The Bench Brief is further deluged with assertions such as: "[Wyeth] enjoyed a boom in sales for Pondimin while knowingly and intentionally permitting the dangerous drug to be prescribed by doctors to their patients; "[Wyeth] was guilty of "corporate avarice" and had "the goal of increasing profits at the expense of human life"; "[Wyeth] exhibited a merciless cold-blooded esprit de corps"; "[Wyeth] also disseminated misleading information to doctors by way of providing it to their drug sales representatives"; and "[Wyeth] sanctioned the spoliation of evidence (i.e., the intentional destruction of evidence)." Plaintiff's Bench Brief at 6, 20-21, 22, 23.

In contrast, in its twenty-four pages, the Bench Brief says virtually nothing about the facts of plaintiff's individual case. Only in passing does it mention on page 1, "Mrs. Clark was prescribed Redux from November 1996 through April 1997. Since May 2000, Mrs. Clark has undergone three echocardiograms which have diagnosed a progressive mitral valve disease and pulmonary hypertension ("PPH")." Plaintiff's Bench Brief at 1. The language of the Bench Brief is the language of someone who intends to present a case seeking to punish Wyeth for malicious conduct under Texas

law. *See* Tex. Civ. Prac. & Rem. Code Ann. §§ 41.001(7) and 41.003(a); *Taiwan Shrimp Farm Vill. Ass'n. Inc. v U.S.A Shrimp Farm Dev., Inc.*, 915 S.W. 2d 61, 72 (Tex. App. 1996). If the Bench Brief is to be believed, plaintiff is not focusing on or expecting to try only a claim for compensatory damages against Wyeth as provided in the Settlement Agreement approved in PTO 1415.

Moreover, on October 3, 2002, less than three weeks before the scheduled trial, Ms. Clark filed her "Second omnibus Supplemental Responses and Requests for Disclosure." This document give further support to Wyeth's contention that plaintiff intends to introduce evidence and make arguments that can only be relevant to a claim for punitive damages. In response to Request No. 3 asking for "the legal theories, and in general the factual bases of the responding party's claims or defenses," she states:

> [a]t all relevant times, Defendants actually knew of the defective nature of their products as herein set forth and continued to design, manufacture, market and sell their products so as to maximize sales and profits at the expense of the public's health and safety in conscious disregard of the foreseeable harm caused by these products. Defendants' conduct exhibits such an entire want of care as to establish that their actions were a result of fraud, ill will, recklessness, or willful and intentional disregard of the plaintiff's rights. Therefore, Plaintiff seeks punitive damages.

Plaintiff Clara Clark's Second Omnibus Supplemental Responses to Request for Disclosure at 8.

Appendix G

Ms. Clark's attorney stated at oral argument in this court on the pending motion that the last sentence quoted above was included in error. Significantly, he did not retract the remainder of the statement. Plaintiff's "legal theories" and "factual bases" clearly show that she is seeking a punitive recovery from Wyeth.

Wyeth has offered Ms. Clark a stipulation in which it would admit a breach of duty to her. In return the stipulation would require her simply to prove that: (1) she had mitral valve regurgitation; (2) Wyeth's product Redux caused the injury; and (3) the amount of her compensable damages. She has refused to agree to this proposal.

Ms. Clark argues that our involvement in this case would amount to improper interference with the evidentiary issues before the state court. We disagree. Under PTO 1415, this court "retains continuing and exclusive jurisdiction over this action and each of the Parties, including AHP [now known as Wyeth] and the class members, to administer, supervise, interpret and enforce the Settlement in accordance with its terms . . . and to enter such other and further orders as are needed to effectuate the terms of the Settlement." Pretrial Order No. 1415 at ¶ 11. Thus, this court has the authority to oversee and supervise the settlement of this class action, including the power to bar class members from pursuing lawsuits in a way which violates the settlement Agreement. Ms. Clark, who is still a class member even after she exercises an intermediate opt-out, cannot circumvent the Settlement Agreement by seeking protection under the state's evidentiary rules. Otherwise, the efficacy of this class action settlement would be seriously undermined. *See In re Prudential Ins.*

Co. of Am., 261 F.3d 355, 367-68 (3d Cir. 2001). Her blatant effort to interject the issue of punitive, exemplary, or multiple damages cannot countenanced. The court will enforce PTO 1415 and enjoin her from doing so in the upcoming trial in the Texas state court.

Wyeth also moves to enforce PTO 1415 to prevent Ms. Clark from pursuing a claim for injuries not permitted under the Settlement Agreement. She seeks to recover for damages to her pulmonary vascular system, independent of her claim for mitral valve regurgitation.[2]

A class member such as Ms. Clark may exercise an intermediate opt-out only if she is "FDA Positive." *See* Settlement Agreement at § IV.D.3.a. The Settlement Agreement's definition of the term "FDA Positive" requires a certain level of regurgitation of either the mitral valve or the aortic valve of the heart. Further, she "may only assert a claim against . . . [Wyeth] based on [her] heart valve . . . which was diagnosed by a Qualified Physician as FDA positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Program." *Id.* at § IV.D.3.c. Wyeth has no problem with her anticipated proof to the extent that it shows pulmonary hypertension secondary to mitral valve regurgitation. However, any pulmonary vascular injuries are otherwise not within the meaning of FDA positive, and she is barred from suing Wyeth with respect thereto.

---

2. Plaintiff concedes she is not seeking damage for Primary Pulmonary Hypertension ("PPH") as defined in the Settlement Agreement. See Pretrial Order No. 1415 at 66-68.

Accordingly, we will also enjoin Clara Clark from pursuing any claim other than those for (1) mitral or aortic heart valve regurgitation and (2) pulmonary hypertension secondary to mitral valve regurgitation. *See Prudential*, 261 F.3d at 367-68.

Appendix G

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MDL DOCKET NO. 1203

CIVIL ACTION NO. 99-20593

IN RE: DIET DRUGS
(PHENTERMINE, FENFLURAMINE
DEXFENFLURAMINE) PRODUCTS
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS CORPORATION

PRETRIAL ORDER NO. 2625

AND NOW, this 16th day of October, 2002, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the motion of Wyeth to enforce PTO 1415 is GRANTED;

(2) the plaintiff Clara Clark, her agents, attorneys, and derivative claimants are ENJOINED in the case of *Clark v.*

Appendix G

Wyeth et al., No. B020182-C, pending in the District Court of Orange County, Texas, from introducing any evidence or making any statement before or argument to the court or jury related directly or indirectly to (a) punitive, exemplary or multiple damages, however described; and (b) malicious, wanton or other similar conduct of Wyeth, however described; and

(3) the plaintiff, her agents, attorneys, and derivative claimants are ENJOINED in the case of *Clark v. Wyeth et al.*, No. B020182-C, pending in the District Court of Orange County, Texas, from introducing any evidence or making any statement before or argument to the court or jury related directly or indirectly to any medical condition of plaintiff caused by Wyeth other than mitral valve regurgitation or pulmonary hypertension secondary to mitral valve regurgitation.

BY THE COURT:

s/ Harvey Bartle, J.

APPENDIX H — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT DENYING PETITION FOR REHEARING DATED JUNE 29, 2004

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Nos. 02-4582, 03-2033, 03-2936, and 03-4362

(02-4582)

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION

Linda Smart, a class member who has exercised her intermediate opt-out rights

Appellant

(03-2033)

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION

Clara Clark, Linda Smart, George M. Fleming, Fleming & Associates, L.L.P., Mike O'Brien and Michael C. Abbott,

Appellants

Appendix H

(03-2936)

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION

Keith K. Barlow, Ruby S. Barlow, Cherry Barnes, Joe Wayne Burton, Nora K. Burton, Lonelle S. James, Michael J. Miller, Kenneth W. Smith, Miller & Associates, Edward A. Williamson, Fenton B. DeWeese, II, The Law Office of Edward A. Williamson, Merrida Coxwell, Charles R. Mullins, Coxwell & Associates, PLLC, and Eugene C. Tullos,

Appellants

(03-4362)

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION

Linda Eichmiller, Brenda Cook, Richard Cook, Doris Caldwell, Susan McCarty, Jim McCarty, Jr., Julia Campbell, Carolyn Winters, Bobby G. Winters, Macy Houston, and John F. Houston, III,

Appellants

Appendix H

SUR PETITION FOR REHEARING

Present: SCIRICA, *Chief Judge*, SLOVITER, NYGAARD, ALITO, ROTH, BARRY, AMBRO, FUENTES, SMITH, CHERTOFF, FISHER, and VAN ANTWERPEN, *Circuit Judges*

The petition for rehearing filed by appellee in the above-entitled cases having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular service not having voted for rehearing, the petition for rehearing by the panel and the Court en banc, is denied.

BY THE COURT,

/s/ Michael Chertoff
Circuit Judge

Dated: June 29, 2004